

**THE COST OF PRESCRIPTION DRUGS: HOW THE  
DRUG DELIVERY SYSTEM AFFECTS WHAT  
PATIENTS PAY**

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**HEARING**  
OF THE  
**COMMITTEE ON HEALTH, EDUCATION,  
LABOR, AND PENSIONS**  
**UNITED STATES SENATE**  
**ONE HUNDRED FIFTEENTH CONGRESS**

FIRST SESSION

ON

THE COST OF PRESCRIPTION DRUGS: FOCUSING ON HOW THE DRUG  
DELIVERY SYSTEM AFFECTS WHAT PATIENTS PAY

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JUNE 13, 2017

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# C O N T E N T S

## STATEMENTS

TUESDAY, JUNE 13, 2017

Page

### COMMITTEE MEMBERS

Alexander, Hon. Lamar, Chairman, Committee on Health, Education, Labor, and Pensions, opening statement .....	1
Murray, Hon. Patty, a U.S. Senator from the State of Washington, opening statement .....	3
Cassidy, Hon. Bill, a U.S. Senator from the State of Louisiana .....	40
Casey, Hon. Robert P., Jr., a U.S. Senator from the State of Pennsylvania .....	43
Young, Hon. Todd, a U.S. Senator from the State of Indiana .....	44
Franken, Hon. Al, a U.S. Senator from the State of Minnesota .....	46
Collins, Hon. Susan M., a U.S. Senator from the State of Maine .....	48
Bennet, Hon. Michael F., a U.S. Senator from the State of Colorado .....	50
Murkowski, Hon. Lisa, a U.S. Senator from the State of Alaska .....	52
Baldwin, Hon. Tammy, a U.S. Senator from the State of Wisconsin .....	55
Warren, Hon. Elizabeth, a U.S. Senator from the State of Massachusetts .....	56
Hassan, Hon. Maggie, a U.S. Senator from the State of New Hampshire .....	58
Murphy, Hon. Christopher, a U.S. Senator from the State of Connecticut .....	60
Sanders, Hon. Bernard, a U.S. Senator from the State of Vermont .....	61
Whitehouse, Hon. Sheldon, a U.S. Senator from the State of Rhode Island .....	62

### WITNESSES

Mendelson, Dan, President, Avalere Health, Washington, DC .....	6
Prepared statement .....	8
Coukell, Allan, Senior Director, Health Programs, The Pew Charitable Trusts, Washington, DC .....	16
Prepared statement .....	18
Howard, Paul, Ph.D., Director and Senior Fellow, Health Policy, Manhattan Institute, New York, NY .....	22
Prepared statement .....	24
Anderson, Gerard, Ph.D., Professor of Medicine, Johns Hopkins University School of Medicine, Baltimore, MD .....	28
Prepared statement .....	29

### ADDITIONAL MATERIAL

Statements, articles, publications, letters, etc.	
John Rother, Executive Director, The Campaign for Sustainable Rx Pric- ing (CSRxP) .....	67
Lobbying Registration Form Submitted by Senator Franken .....	73
Response to questions of Senator Alexander by:	
Dan Mendelson .....	76
Allan Coukell .....	77
Paul Howard .....	80
Gerard Anderson .....	82

Response by Dan Mendelson to questions of Senator Isakson .....	83
Response to questions of Senator Sanders by:	
Dan Mendelson .....	83
Paul Howard .....	83
Gerard Anderson .....	85

## **THE COST OF PRESCRIPTION DRUGS: HOW THE DRUG DELIVERY SYSTEM AFFECTS WHAT PATIENTS PAY**

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**TUESDAY, JUNE 13, 2017,**

U.S. SENATE,  
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,  
*Washington, DC*

The committee met, pursuant to notice, at 10:07 a.m. in room SD-430, Dirksen Senate Office Building, Hon. Lamar Alexander, chairman of the committee, presiding.

Present: Senators Alexander, Collins, Cassidy, Young, Murkowski, Scott, Murray, Sanders, Casey, Franken, Bennet, Whitehouse, Baldwin, Murphy, Warren, Kaine, and Hassan.

### **OPENING STATEMENT OF SENATOR ALEXANDER**

The CHAIRMAN. Good morning.

The Senate Committee on Health, Education, Labor, and Pensions will please come to order.

Today's hearing is about how Americans pay for prescription drugs and where that money goes. This is a bipartisan hearing, which means Senator Murray and I have agreed on the topic, and we have agreed on the witnesses.

Senator Murray and I will each have an opening statement, and then we will introduce the witnesses. We hope you will summarize your remarks in about 5 minutes each, which will leave Senators time to engage in a conversation with you. Senators will have about 5 minutes of questions as we go around.

The committee is having this hearing in response to a bipartisan request from a number of members of the committee. That request was led by Senator Cassidy and Senator Franken, but it included Senators Collins, Baldwin, Murkowski, Whitehouse, Capito, Sanders, Enzi, and Warren. All suggested we should have this hearing.

This will be the first of three hearings we plan to hold on prescription drug costs. The purpose of this first hearing is to see if we can better understand a complex subject and agree on some basic facts. Americans want to know who pays for prescription drugs and where that money goes.

Next month, the committee will hold a second hearing to hear about the process, beginning with the manufacturer's development of a drug, the different steps through which the drug travels before arriving in a patient's hands, how this is paid for, and what the costs are at each step along the way.

In the fall, we will hold a third hearing to hear from Norm Augustine and consider a report that he is leading from the National Academy of Sciences. The report is the outcome of a project called, "Ensuring Patient Access to Affordable Drug Therapies."

The United States leads the world in innovative biomedical and pharmaceutical research and development, and American patients benefit from having access to most lifesaving drugs first.

Our country produces more than 20 percent of the world's wealth, and it is well known that we spend a large share of that wealth on our health, a much larger share than many other advanced countries.

In 2015, according to the Centers for Medicare and Medicaid Services, healthcare spending totaled nearly 18 percent of our country's Gross Domestic Product. Prescription drugs were about 10 percent of that spending and closer to 15 percent when you consider prescription drugs administered in hospitals and doctors' offices.

At around the same time in 2014, the World Bank showed the United Kingdom was spending 9.8 percent of its domestic product on health care, Germany 11.1 percent, and Finland 9.6 percent.

More than 4 billion prescriptions are written for drugs each year for Americans who then receive these drugs at 60,000 drug stores, from doctors or hospitals, or from online pharmacies. The total cost to the overall health system of these prescriptions each year is \$450 billion to be paid by taxpayers, by patients, by hospitals, and insurers, among others.

Many of these are truly miracle drugs. They cure Hepatitis C, keep cancer at bay, stop a stroke, and prevent heart attacks.

According to the Centers for Disease Control and Prevention, Americans are living on average 10 years longer than their life expectancy in the 1950s. Access to innovative drugs is a major reason why.

In 2003, Congress passed the Medicare Part D Prescription Drug program, which provides drugs to about 41 million Americans over 65 years of age. The Congressional Budget Office estimates that prescription drugs from those on Medicare will cost taxpayers and patients about \$94 billion this year.

While safe prescription drugs have become an integral part of American family lives today, all of this is relatively new.

In 1906, Congress passed the Federal Food and Drug Act, which added regulatory responsibilities to the Food and Drug Administration's scientific mission by prohibiting interstate commerce in misbranded and adulterated food, drugs, and drinks.

In 1938, this was updated to require a manufacturer to show that each new drug must be safe before it comes to the market, starting a new system of drug regulation.

It was only in 1941 that the Food and Drug Administration, in response to the Insulin Amendment, first began to require that a drug be tested and certified for purity and potency, the first being insulin for the treatment of diabetes. During the next decade and beyond came approval of mass produced penicillin, other antibiotics, and a broader range of drugs.

Developing and approving a drug today is a lengthy and costly process. According to the Tufts Center, from the beginning of the

research and development phase through FDA approval, developing a new drug takes, on average, 10 to 15 years and can cost close to \$2.6 billion. Let me say that again. According to the Tufts Center, from beginning the research and development phase through FDA approval, developing a new drug takes, on average, 10 to 15 years and can cost close to \$2.6 billion.

Success is far from guaranteed. Fewer than 12 percent of drugs that make it to Phase I clinical trials are finally approved by the FDA.

According to Research!America, the United States spent \$159 billion on medical health and medical research and development in 2015. The National Institutes of Health funded roughly 19 percent of that; 8 percent was funded by universities and independent research institutes; 5 percent came from other Federal and State governmental entities; 4 percent from foundations and professional societies; 15 percent, or \$24 billion, was funded by the medical device industry and other non-biopharma private industry. The largest share of this research, 49 percent or \$78 billion, was funded by the biopharmaceutical industry.

It is from these investments that we can expect to see the medical miracles that NIH Director Francis Collins has predicted will occur during the next decade: Artificial pancreas for those with diabetes; new cancer cures; a vaccine for Zika; a vaccine for HIV/AIDS; and a universal flu vaccine; medicines to identify individuals at risk for Alzheimer's before symptoms as well as provide effective therapies to slow or even prevent the disease.

Over the years, this committee in a bipartisan way has produced important laws to reduce the cost of drugs before they are approved by the FDA.

For example, last year's 21st Century Cures legislation; the Hatch-Waxman Act, which created the generic drug industry; and multiple FDA User Fee Agreements, which have helped fund the FDA and modernize our drug and device approval process.

Our focus today is different. It is on what happens to the cost of the drug after it is approved by the FDA. We will examine the path an approved drug takes from the manufacturer to patient, and how this affects what the patient pays.

We hope to agree on some basic facts such as whether prescription drug prices are going up or down, and by how much?

We want to know as prescription drugs move from FDA approval through a complex process and into the hands of patients, where does the money go?

What are rebates and what is their impact on consumers?

Who actually pays the cost of prescription drugs?

This is a discussion that affects the well-being of every American family. It is important that we work together to conduct this fact finding in a bipartisan way.

Senator Murray.

#### OPENING STATEMENT OF SENATOR MURRAY

Senator MURRAY. Well, thank you, Chairman Alexander.

As I have made clear, the burden of prescription drug costs is a huge problem. I hear about it from far too many families in my home State and across the country.

I am glad we are having this discussion today. It is something Democrats on this committee have wanted to do for a very long time, and I am pleased that we are working on some additional hearings. I am hopeful this work can lead to some real bipartisan progress.

I want to express my appreciation, in particular, to Senator Franken, who has been underscoring the importance of hearing from actual patients about the struggle they face in affording the medication they need. Our work on this committee is strongest when patients' and families' voices are part of this process. I agree, we should make sure that that happens as our discussion on this continues.

I also want to note that today's hearing, on a topic central to families' experience with our healthcare system, takes place in the midst of a pivotal and deeply concerning moment for our healthcare system as a whole.

My colleagues on the other side of the aisle appear to be dead set on jamming their version of Trumpcare through the Senate in a matter of days. They have held no hearings, engaged in no public debate, and provided no information for people across the country to understand what this all-male, Republican working group has in store for their health and financial security.

For comparison, during the debate on the Affordable Care Act, we held 57 bipartisan meetings, hearings, roundtables, and walkthroughs on the text in this committee alone, and another 53 in the Finance Committee. There were 25 consecutive days of debate on the Senate floor.

Mr. Chairman, I just have to say this morning, I cannot say how strongly enough, how unacceptable this is, and I will be very loud and vocal about this, and continue to push for hearings and open debate on the Senate version of the Trumpcare bill.

In fact, given this committee's long track record of bipartisan successes, I have to say I am really surprised and disappointed that we are allowing this to happen. I know you are part of the process that is going on in secret.

I just have to tell you, people deserve public debate about the future of our healthcare system especially since all Senate Republicans' promises to the contrary, it unfortunately sounds like this legislation is based on the very same principles as the disastrous House Trumpcare bill, including higher costs for families, especially seniors and people with pre-existing conditions.

Millions of people will be kicked off Medicaid. Insurance companies, once again, will be allowed to charge people more for basic healthcare like maternity care or mental health services, or as we are talking about today, the expensive, but essential prescription drugs they need. All to give a massive tax break to special interests in the health industry and hand President Trump a hollow political win.

Let us be clear, as many of my democratic colleagues have said, this is not a healthcare bill. It is an attack on families, and health, and financial security.

What I really do hope is over the next several weeks as Republicans hear from many people across the country who would be devastated by this bill that they choose to change course.

I will say again, Democrats are ready, like we always have been, to work together on continuing to fix our healthcare system in ways that make our healthcare system more affordable while preserving quality of care and getting more people covered.

We cannot begin that conversation until Republicans reverse course and stop trying to take our healthcare system backward with a reckless repeal effort and politically motivated sabotage that is creating damaging uncertainty in our markets and driving up our families' costs.

I sincerely hope that this effort is backed off because there are urgent challenges like the one we are talking about today that really deserve our attention.

Today's astronomically high prescription drug prices are an unsustainable burden on our healthcare system as a whole and especially on the patients and families that we represent. I have heard from far too many families who are forced to choose between high-priced medication, paying the bills, or putting food on the table. That really is no choice at all. So as I said before, it is well past time for this conversation and for progress on this issue.

As we discuss the reality of the high prices too many of our constituents are paying for prescription drugs, I do think it is important to note that President Trump is wrong to point the finger at the FDA.

Over two-thirds of new drugs are now launched in the United States, more than triple the rate in the early 1990s, when the first user fee programs were enacted. The Agency has reduced the backlog of generic applications to help get competitive, cheaper drugs to patients.

I am pleased this committee took steps in the FDA Reauthorization Act to increase transparency and foster more competition in the generic market, thanks to the work of Senators McCaskill, Collins, and Franken.

We should always look for ways to get more safe, effective treatments to patients as quickly as possible. The FDA approval process is the wrong place to look if we really want to tackle high drug prices.

I am proud that a number of Democrats on this committee have put forward a number of ideas to get at the root of the problem, which are the high prices set by drug manufacturers.

Democrats have introduced legislation, including bipartisan legislation, to demand more transparency from pharmaceutical companies about what is behind the soaring drug prices, allow Medicare to negotiate fair prices for prescription drugs, and to prevent manufacturers from engaging in price gouging and more.

I am grateful to all the members of this committee who have worked together, and across the aisle, to advance these policies, which would make a real difference to the patients and families we serve.

Mr. Chairman, I am glad to hear that today's conversation on the burden of prescription drug prices will not be the last on this committee, but there is a lot more we can do and should do together to tackle this issue.

Again, it is deeply disappointing that instead of working with Democrats to bring down the price of prescription drugs for fami-

lies, and the other challenges that so many people face in the healthcare system, my Republican colleagues are very focused on a partisan, political, and damaging effort to enact Trumpcare within the next few weeks without any public scrutiny.

I really hope that instead of working to jam Trumpcare legislation through, according to an independent CBO analysis, is a direct threat to the lives, and health, and financial security of millions of people. That you all will reconsider, reverse course, and work with us on solving problems.

If you do, if you drop your efforts to sabotage the healthcare system and enact Trumpcare, and if you are ready to tackle the challenges by bringing down the healthcare costs for families, we are at the table. We are ready to work and we want to do that.

Thank you very much, Mr. Chair.

The CHAIRMAN. Thank you, Senator Murray.

I will repeat. This is a hearing requested by Democrats as well as Republicans on drug prices. It is a bipartisan hearing and it is one in which Senator Murray and I have agreed on the witnesses.

We welcome the witnesses. I will introduce you now. Each witness will have up to 5 minutes to give his testimony. We are going to go from left to right, but let me introduce them this way.

Dan Mendelson is the first witness we will hear from. He is the president of Avalere Health, a leading healthcare consulting firm specializing in strategy, policy, and data analysis for life sciences, health plans, and providers. Prior to founding Avalere in 2000, he served as Associate Director for Health at the White House Office of Management and Budget.

Next, we will hear from Allan Coukell, senior director of health programs at The Pew Charitable Trusts. The Trusts is an independent, nongovernmental organization that conducts analysis to provide useful data on issues and trends in public policy. Mr. Coukell oversees initiatives at The Pew related to drug and medical device innovation and safety, the pharmaceutical supply chain, FDA, specialty drugs, as well as other efforts related to health costs and delivery.

Third, Dr. Paul Howard is senior fellow and director of health policy at the Manhattan Institute. Dr. Howard has written on a wide variety of medical policy issues including FDA reform, biopharmaceutical innovation, consumer-driven healthcare, Medicare and Medicaid reform.

Last, we will hear from Dr. Gerard Anderson, professor of health policy and management at the Johns Hopkins University Bloomberg School of Public Health and Medicine. Dr. Anderson is also director of the Johns Hopkins Center for Hospital Finance and Management. He is currently conducting research on drug pricing, chronic conditions, comparative insurance systems in developing countries, medical education, and healthcare payment reform.

Mr. Mendelson, let us start with you and go down the line. Welcome.

**STATEMENT OF DAN MENDELSON, PRESIDENT, AVALERE  
HEALTH, WASHINGTON, DC**

Mr. MENDELSON. Thank you very much.

Chairman Alexander, Ranking Member Murray, members of the committee, thank you for the invitation to discuss how the healthcare delivery system affects what consumers pay for prescription drugs.

I also want to thank the incredible team at Avalere Health whose passion to be the essential voice improving healthcare is being realized today. Of course, my comments are my own and do not reflect the views of my organization or our parent company, Inovalon.

My full testimony has plenty of detail about the current system, including trends in pricing that address a lot of the initial questions that you asked, Senator Alexander.

I have chosen to focus my comments today on three items—aspects of the delivery system that are within the purview of this committee. First, let us focus on benefit design.

In recent years, payers have been under increasing pressure to meet consumer demand for constrained premium growth. Deductibles and cost sharing for medications have increased substantially across both commercial and Government payment systems.

Growth and exposure to cost by consumers is seen across traditional employer plans, Government plans, as well as high deductible plans. Cost sharing for drugs is typically higher on a percentage basis from that for hospital or other medical care. It is not uncommon that you will see a patient paying more for a chronic medication than they would for a surgery, even though the surgery costs the healthcare system more.

One other thing to consider is that cost sharing is typically calculated on the basis of the full price of the drug before accounting for rebates or discounts offered by the manufacturer. There are some exceptions to this. For example, CVS Health can adjudicate rebates at the point of sale and give the consumer a net price.

There is a question, why should an individual with a chronic illness, who needs a high cost medication, not benefit from the price concessions given by a pharmaceutical company on that particular product in the competitive class?

We also need to think carefully about the incentives that benefit designs give patients. For example, if a patient with Multiple Sclerosis, rheumatoid arthritis, or anemia has to use a drug in its class and the only drugs available have a 35 percent co-pay, why should they have to pay that percentage co-pay even though the only reason that they are doing it is because they have this particular condition? Why should a patient have to pay more than the cost of a generic drug for a generic drug in a design?

These are all questions that, I think, are important.

My second area of focus is competition. Speeding the approval of second and third branded drugs to market would dramatically expedite competition and result in price concessions from manufacturers.

You saw this with the second drug in the Hepatitis C category when it was approved. The net prices of these products were reduced dramatically.

A second area, that I know is a strong interest and within the purview of this committee, is generic pharmaceuticals where ap-

proving generics on an expedited basis in various places does create dramatic consumer surplus. Then finally, biosimilar competition and expediting these drugs to market.

All of these are really very important and an important facet of the delivery system because it is in this competition that drug prices actually come down over a period of time.

My final area of focus is value-based contracting. We are in the midst of a very dramatic transformation in healthcare from pay for volume to pay for value. This is of direct relevance, I believe, to the cost of pharmaceuticals. We see this in Medicare Advantage.

For example, Medicare Advantage plans have to do well on their quality metrics in order to have a viable business. A lot of these quality metrics are being driven by things like the prescription of generic cholesterol lowering medications.

In fact, we see many plans actually paying substantial amounts of money to create programs to get patients to take these medications. That is the kind of design that, benefits the program and the kind of design that is important in the future.

One other aspect that I would like to mention is data. Using the patient's data to identify gaps in care, doing analytics on that basis, and then ensuring that the patient that actually needs the medication is getting what they need, also has tremendous promise to reduce total health system costs, and merits the focus of this committee.

There are many regulations right now that actually prevent manufacturers and health plans from entering into the kinds of arrangements that can actually reduce cost for consumers, and they do merit the focus of the committee.

I want to close with one comment about process. Underlying all of our work is the view that collaboration is absolutely critical to fashioning good policy. So in the work that we do, we are always looking for solutions that will be embraced by a broad array of policies. We are a nonpartisan, nonpolitical organization and try to focus in that way as well.

I am excited to continue supporting this discussion as it evolves over the course of the three hearings.

Thank you very much.

[The prepared statement of Mr. Mendelson follows:]

#### PREPARED STATEMENT OF DAN MENDELSON

##### SUMMARY

The focus of this testimony is how the healthcare delivery system affects what consumers pay for prescription drugs. Consumer exposure to drug costs is determined by benefit design, the competitiveness of drug classes, and approaches to provider payment, among other factors. Health system change, including outcome-based payment and value-based contracting, has potential to incent better alignment between consumers and providers.

##### BENEFIT DESIGN

In recent years, payers have been under increasing pressure to meet consumer demand for constrained premium growth through changes to benefit design. Deductibles and cost sharing for medications have increased substantially across government and commercial payers, leading many consumers to pay more out-of-

pocket for drugs.<sup>1</sup> For medications subject to the deductible or coinsurance, consumer cost sharing is typically calculated on the full cost of the drug before accounting for rebates or discounts offered by the manufacturer to the health plan or pharmacy benefit manager. Of course, consumer costs are also importantly determined by the pricing decisions made by pharmaceutical companies prior to entry of product into the supply chain.

#### MARKET COMPETITION

Increased competition in the pharmaceutical markets holds promise for substantially reducing costs. Speeding the approval of the second- and third-branded drugs in a therapeutic class would expedite competition and lead to more rapid price concessions. Ensuring a continued robust market for generic pharmaceuticals is vital for effective cost management and improvement of population health outcomes. Finally, there is much promise for consumers in effective biosimilar competition as patents on key biologics expire.<sup>2</sup>

#### MARKET DRIVEN SOLUTIONS

As payers strive to link payment to value, healthcare stakeholders must agree on how to define and measure the value of any given product or service. Importantly, in addition to reflecting patient perspectives on what constitutes value, assessments of value should consider not only cost of the medication but also total cost of care, including pharmacy and medical spending.

Outcomes-based contracts also represent a significant opportunity to shift away from prescription drug list pricing toward value-based reimbursement models. Avalere recently found that 70 percent of health plans have favorable attitudes toward outcomes-based contracts, and one-half of health plans indicate they have outcomes-based contracts already in place or are actively negotiating them.<sup>3</sup> Existing regulatory barriers, including standards related to government price reporting and the Anti-Kickback Statute, presently hamper further development of this trend.<sup>4</sup>

Health system change is increasingly assigning value to improvements in population outcomes for common medical conditions, and many of these outcomes can be effectively achieved through better use of medication. Further alignment of stakeholder interests around the use of pharmaceuticals holds promise to benefit consumers as payment systems evolve toward value-based designs.

#### INTRODUCTION

The prices that consumers pay for drugs are determined jointly by health system design, pharmaceutical company pricing, and decisions by health plans, pharmacy benefit management (PBM) practices, and other transactions involving distributors and pharmacies along the supply chain. As the healthcare system moves from volume- to value-based payments, the incentives underlying many of these market-based pricing decisions are also changing rapidly. The purpose of this testimony is to elucidate how these factors ultimately determine the prices paid by the consumer for drugs.

#### HOW NET PRICES TO THE CONSUMER ARE DETERMINED

The pharmaceutical supply chain is the means through which prescription medicines are delivered to patients (Figure 1).<sup>5</sup> Drugs typically originate in manufacturing sites; are transferred to wholesale distributors; stocked at retail, mail-order, and other types of pharmacies; subject to price negotiations and processed through quality and utilization management screens by PBMs; dispensed by pharmacies;

<sup>1</sup>Avalere Health, "Consumer Costs Continue to Increase in 2017 Exchanges," January 18, 2017, <http://avalere.com/expertise/life-sciences/insights/consumer-costs-continue-to-increase-in-2017-exchanges>.

<sup>2</sup>Avalere Health, "Five Obstacles to Competition in the United States Biologics Market," <http://avalere.com/expertise/life-sciences/insights/five-obstacles-to-competition-in-the-united-states-biologics-market>.

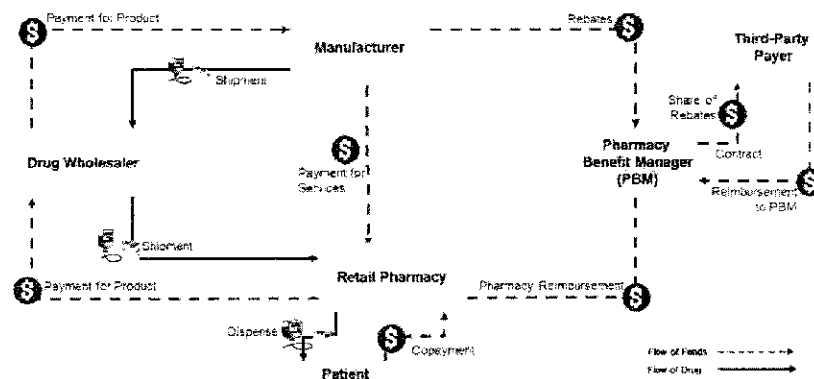
<sup>3</sup>Avalere Health, "Health Plans are Actively Exploring Outcomes-Based Contracts," May 30, 2017, <http://avalere.com/expertise/life-sciences/insights/health-plans-are-actively-exploring-outcomes-based-contracts>.

<sup>4</sup>Eli Lilly and Company and Anthem, "Promoting Value-Based Contracting Arrangements," January 2016, <https://lillypad.lilly.com/WP/wp-content/uploads/LillyAnthemWP2.pdf>.

<sup>5</sup>Avalere Health (formerly The Health Strategies Consultancy), "Follow the Pill: Understanding the US Commercial Pharmaceutical Supply Chain," Kaiser Family Foundation, March 2005.

and ultimately delivered to and taken by patients. There are many variations on this basic structure, as the players in the supply chain are constantly evolving, and commercial relationships vary considerably by geography, type of medication, and other factors. The pharmaceutical supply system is complex and results in price variability across different payers and consumers.

FIGURE 1. RETAIL, PHARMACY BENEFIT PRODUCT AND REIMBURSEMENT FLOW



#### DRUG SPENDING TRENDS

Drugs dispensed in the pharmacy and medical benefit account for approximately 13 percent of total U.S. healthcare costs.<sup>6</sup> This frequently cited figure uses total national health expenditures as a basis for calculating the percentage. Other experts sometimes use a subset of national health expenditures or total medical claims as the denominator, which accounts for the range of percentages often cited in this context. In recent years, new innovations have increased spending on specialty medications, which now account for \$384 of the \$895 per person per year spent on drugs.<sup>7</sup> These trends particularly impact the Medicare program, in which the Medicare Trustees project that Part D spending will grow at an average annual rate of 9.2 percent from 2016–25.<sup>8</sup>

Over the past 5 years, list prices for protected pharmacy benefit drugs have increased 11.5 percent, while net prices have increased 6.1 percent (Figure 2).<sup>9</sup> The difference is the result of rebates and other discounts from manufacturers to public and private payers. These considerable differences between list and net pricing trends show the power that competition and payer negotiation have on drug prices. As multiple products for a given indication come to market, plans and PBMs may negotiate rebates from manufacturers in exchange for preferred formulary placement and improved access. Typically, payers use these price concessions to reduce overall premiums, but the rebates are not shared directly with patients at the point of sale. As a result, most patients who fill a prescription are paying cost-sharing based on list, rather than net, price.

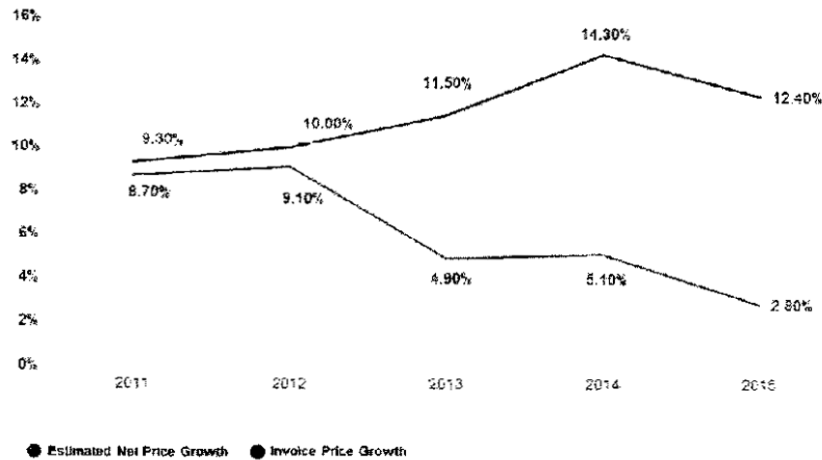
<sup>6</sup>Centers for Medicare & Medicaid Services, National Health Expenditure Data. NHE Tables. December 2016. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>; Altarum Institute Center for Sustainable Health Spending, “A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail,” May 2017 (Addendum II).

<sup>7</sup>Quintiles IMS Institute. “Medicines Use and Spending in the US,” May 2017. <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021#form>.

<sup>8</sup>Medicare Trustees. “2016 Annual Report,” June 2016. <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reporttrustfunds/downloads/tr2016.pdf>.

<sup>9</sup>Quintiles IMS Institute. “Medicines Use and Spending in the US,” April 2016, <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020>.

FIGURE 2. LIST VS. NET PRICE GROWTH, PROTECTED PHARMACY BENEFIT DRUGS, 2011–2015



## BENEFIT DESIGN

Insurance benefit designs increasingly expose consumers to the full cost of their medicines through percentage co-payments for drugs. Further, consumer exposure to out-of-pocket costs has increased as deductibles have grown across benefit programs.

In recent years, payers have been under increasing pressure to meet consumer demand for constrained premium growth through changes to benefit design. In particular, the financial crisis accelerated adoption of high deductible health plans (HDHPs) among employers.<sup>10</sup> In addition, the patient protections put in place under the Affordable Care Act (ACA) required payers to focus on benefit design as a way to offer competitive premiums in an environment where price-sensitive consumers focus on monthly costs. Consumers are therefore paying more out-of-pocket for prescription drugs as deductibles increase and use of coinsurance for drugs becomes more common. Of course, other factors unrelated to the delivery system effects that are the focus of this hearing are also responsible for increased payment by consumers—such as the cost of newly launched products and the increases in list prices over time referenced in cost sharing.

Health plan deductibles have grown steadily over time. Among individuals with employer coverage, average deductibles increased 49 percent over the last 5 years, rising to \$1,478 in 2016.<sup>11</sup> For individuals enrolled in coverage through exchanges, 2017 unsubsidized silver plans had average deductibles of \$3,703—a 20 percent increase from 2016 and a 49 percent increase from 2014 levels.<sup>12</sup> Importantly, 56 percent of exchange consumers receive cost sharing reduction subsidies (CSRs), which lower deductibles to between \$243 and \$3,070 on average based on consumer income. The American Health Care Act (AHCA) would repeal the CSRs.<sup>13</sup>

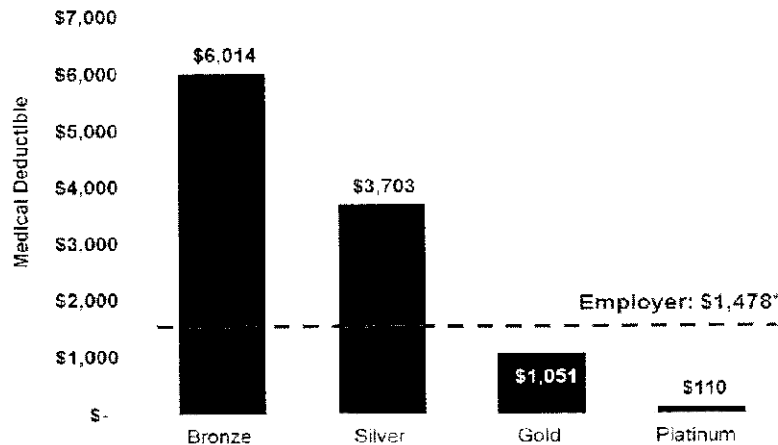
<sup>10</sup> Bureau of Labor Statistics. “Consumer-Driven Health Care: What Is It, and What Does It Mean for Employees and Employers?” October 2010. <https://www.bls.gov/opub/mlr/cwc/consumer-driven-health-care-what-is-it-and-what-does-it-mean-for-employees-and-employers.pdf>.

<sup>11</sup> Kaiser-HRET. “2016 Employer Health Benefits Survey,” September 2016. <http://www.kff.org/health-costs/press-release/average-annual-workplace-family-health-premiums-rise-modest-3-to-18142-in-2016-more-workers-enroll-in-high-deductible-plans-with-savings-option-over-past-two-years/>.

<sup>12</sup> Avalere Health, “Consumer Costs Continue to Increase in 2017 Exchanges,” January 18, 2017. <http://avalere.com/expertise/life-sciences/insights/consumer-costs-continue-to-increase-in-2017-exchanges>.

<sup>13</sup> Avalere Health, “AHCA Will Remove Low-Cost Sharing Guarantees for Low-Income Individuals,” May 16, 2017. <http://avalere.com/expertise/managed-care/insights/ahca-will-remove-low-cost-sharing-guarantees-for-low-income-individuals>.

Figure 3. Average Combined Deductibles for Exchange Plans by Metal Level in 2017 Compared to Employer Plans in 2016<sup>14</sup>



For drugs dispensed in the deductible, consumers pay the full cost of the drug based on the price negotiated by the pharmacy or provider. This price does not reflect rebates or discounts offered by the manufacturer to the health plan or PBM.<sup>15</sup> As a result, patients who choose plans with significant deductibles and also use specialty and high-cost medications can face large bills for these drugs early in the calendar year, which may cause them to forego care or prevent them from complying with prescribed drug regimens. Research shows that high out-of-pocket costs reduce medication adherence and use.<sup>16</sup> Indeed, only 9 percent of patients without a deductible abandon prescriptions, while patients with a deductible abandon medications at a rate of 23 percent and 27 percent for brand and specialty drugs respectively.<sup>17</sup>

Once consumers spend through the deductible, they continue to pay cost-sharing as they access products and services. Increasingly for prescription drugs, this cost sharing takes the form of coinsurance, in which individuals pay a percentage of the cost of the drug rather than a fixed dollar copayment. Coinsurance is calculated based on the negotiated, rather than net, price.

As the number of specialty medications on the market has increased, so too has the use of specialty drug tiers. In 2016, 43 percent of employer plans had separate tiers for these products. Among those plans, 46 percent charge coinsurance averaging 26 percent.<sup>18</sup> This trend is more pronounced in the exchange markets where 84 percent of all 2017 silver plans charge coinsurance for specialty drugs with average coinsurance amounts of 37 percent of the drug cost (Figure 4).<sup>19</sup>

<sup>14</sup> Avalere PlanScape®, a proprietary analysis of exchange plan features, December 2016 and Kaiser-HRET, “2016 Employer Health Benefits Survey.” Avalere analyzed data from the FFE Individual Landscape File released October 2016 and the California and New York State exchange websites.

<sup>15</sup> Negotiated price does not reflect rebates or post point-of-sale price concessions. Discounts knowable at the point of sale are included in negotiated price.

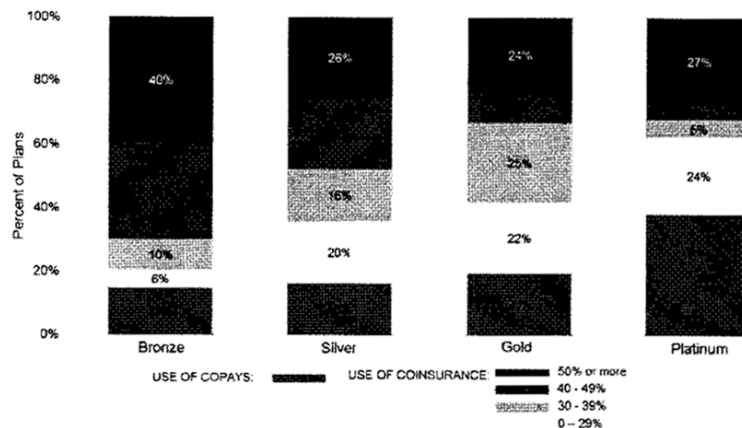
<sup>16</sup> Goldman DP, Joyce GF, Zheng Y. Prescription drug cost sharing: Associations with medication and medical utilization and spending and health. *Jama*. 2007;298(1):61–9. Kirkman MS, Rowan-Martin MT, Levin R, et al. Determinants of adherence to diabetes medications: Findings from a large pharmacy claims database. *Diabetes Care*. 2015;38(4):604–9. Li P, Schwartz JS, Doshi JA. Impact of Cost Sharing on Therapeutic Substitution: The Story of Statins in 2006. *Journal of the American Heart Association*. 2016;5(11).

<sup>17</sup> Quintiles IMS Institute. “Medicines Use and Spending in the US,” May 2017. <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021#form>.

<sup>18</sup> Kaiser-HRET. “2016 Employer Health Benefits Survey,” September 2016. <http://www.kff.org/health-costs/report/2016-employer-health-benefits-survey/>.

<sup>19</sup> Avalere PlanScape®, a proprietary analysis of exchange plan features, December 2016. Avalere analyzed data from the FFE Individual Landscape File released October 2016 and the California and New York State exchange websites.

Figure 4. Prescription Drug Cost Sharing on Specialty Tier in Exchange Plans



Notably, the ACA implemented a maximum out-of-pocket limit that caps consumer costs across all healthcare services. This limit offers important protection for chronically ill individuals against catastrophic healthcare costs, but does not extend to Medicare beneficiaries. In addition, as benefits expose consumers to increasing costs, use of copay assistance has also risen. IMS reports that 19 percent of commercial brand drug claims in 2016 included the use of a copay coupon to reduce out-of-pocket costs, with significant variation across therapeutic classes.<sup>20</sup>

Across all forms of insurance, consumer out-of-pocket burden is not evenly distributed among covered benefits. Outpatient prescription drugs are covered at lower percentage rates than some other services. One study, using data from 2014, showed that for all drugs covered by insurance in the United States, consumers paid 13 percent of every dollar compared to 3 percent for hospital stays, 7 percent for emergency care, and 14 percent for physician office visits.<sup>21</sup> These data demonstrate the role of benefit design in shaping consumer perception of cost.

#### MARKET COMPETITION

Consumer experience with drug costs is importantly determined by the competitiveness of drug classes. Increased competition in a class—whether through the introduction of a generic or a competitive branded product—typically results in substantial net price reductions, particularly for legacy products.

Health plans and PBMs play an important role in negotiating drug rebates and discounts on behalf of employees, individual market consumers, and government programs. This role is exemplified when a second-to-market brand medication enters the market. While underlying data is proprietary, recent experience associated with the Hepatitis C market suggests competition among brands led to significant reductions in net prices for innovative medicines.<sup>22</sup> In addition, managed care entities incent use of lower cost alternatives, including generics. Health plans and self-insured employers expect that their PBMs will effectively manage cost—and often compensate on that basis.

In addition to managed care stakeholders, drug approval and exclusivity processes introduce competition into the marketplace. For traditional, small-molecule drugs, the generic approval system created under the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the Hatch-Waxman Act) has been effective at maintaining commercial incentives for drug development through market exclu-

<sup>20</sup> Quintiles IMS Institute. “Medicines Use and Spending in the US,” May 2017. <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021#form>.

<sup>21</sup> Avalere analysis of Medical Expenditure Panel Survey, 2014, from the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality. <https://meps.ahrq.gov/mepsweb/>. Accessed February 2017. Analysis includes all individuals with any source of health care coverage, including public and private.

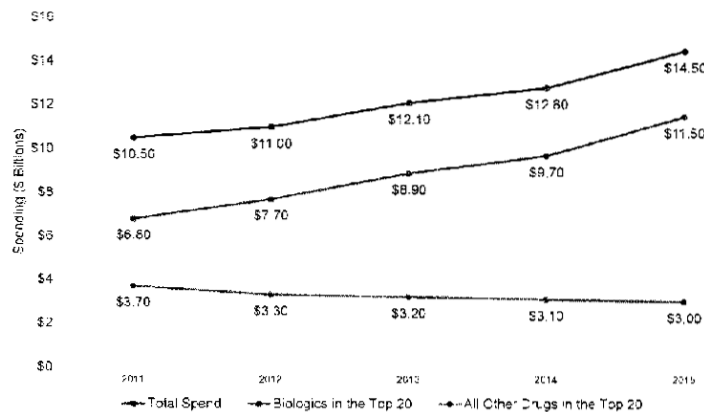
<sup>22</sup> Humer, Caroline, “HCV price war will save an estimated \$4 billion,” Reuters, January 2015. <http://www.reuters.com/article/us-express-scr-hepatitis-idUSKBN0KV26X20150122>.

sivity, while creating strong pricing pressure through generic competition later in the product lifecycle. Despite concerns during the passage of Hatch-Waxman, the number of approved New Drug Applications (NDAs) has remained relatively constant in over three decades since its enactment, and generic drugs now comprise 89 percent of all drugs dispensed in the United States.<sup>23</sup> On average, drug prices decrease by 51 percent within 12 months of generic competition and decrease by nearly 80 percent within 6 years. In the past 10 years, cost savings from generics are estimated at \$1.68T.<sup>24</sup>

There are a few exceptions where competition does not produce dramatic cost savings for patients in today's environment. First, is the case of generics with limited or no competition, in which the traditional competitive pricing pressures do not always apply.<sup>25</sup> FDA Commissioner Scott Gottlieb has already indicated his support of initiatives to focus on speeding entry of second-to-market generics.<sup>26</sup> For products that have not yet reached the end of their exclusivity, the FDA may also be able to accelerate approval of the second product to market to encourage more rapid competition and price concessions from branded drugs.

Biologics are another area of focus for improved competition. Biologics have grown to represent 79 percent (\$11.5B) of Medicare Part B (Figure 5) and 21 percent (\$8.7B) of Medicare Part D spending for the top 20 drugs in each program.<sup>27</sup>

FIGURE 5: MEDICARE TOP 20 PART B SPENDING TRENDS



In 2010, a biosimilar approval pathway was created with an expectation that a multi-source competitive market could offer potential savings for the U.S. health system.<sup>28</sup> However, obstacles remain that may limit the pricing benefits of a truly competitive biologics market—including both innovator and biosimilar products:

1. *Complexity of Development:* While generics typically experience a 3–5 year development timeline and a cost of \$1–5 million, biosimilar development requires 8–

<sup>23</sup> FDA. "Summary of NDA Approvals & Receipts, 1938 to the present." 2011. <https://www.fda.gov/aboutfda/whatwedo/history/productregulation/summaryofndaapprovalsreceipts1938tothepresent/default.htm>. Last accessed 2 May 2017.

<sup>24</sup> Ostroff, Stephen. "Building a Modern Generic Review Process." Food and Drug Administration, FDA, 4 Feb 2016. Web. 28 April. 2017. <https://blogs.fda.gov/fdavoices/index.php/2016/02/building-a-modern-generic-drug-review-process/>.

<sup>25</sup> Government Accountability Office. "Generic Drugs under Medicare," August 2016. <http://www.gao.gov/assets/680/679022.pdf>.

<sup>26</sup> Edney, Anna, "Drug Prices Become Target for FDA as Chief Expands Purview," Bloomberg, June 2017. <https://www.bloomberg.com/news/articles/2017-06-05/drug-prices-become-target-for-fda-as-chief-expands-agency-s-view>.

<sup>27</sup> Avalere Health, "Five Obstacles to Competition in the United States Biologics Market," <http://avalere.com/expertise/life-sciences/insights/five-obstacles-to-competition-in-the-united-states-biologics-market>.

<sup>28</sup> The biosimilar pathway was created by the Biologics Price Competition and Innovation Act (BPCIA) as Title VII of the Patient Protection and Affordable Care Act in 2010. Available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM216146.pdf>.

10 years and potentially costs \$200 million or more due to the complexity of the molecules involved.<sup>29</sup> As a result, it is unlikely that biosimilars pricing will ever match the level of savings in the generic pharmaceutical market.

2. *Prescribing Patterns*: Patient and provider reticence to switch from a reference biologic to a biosimilar may also hamper market competition, though this manifests itself differently in different therapeutic areas.

3. *Interchangeability*: As of yet, the FDA has not issued final guidance on how products would be designated as interchangeable, which limits the potential for automatic substitution and associated cost savings.

4. *Physician Reimbursement Model*: Within Medicare Fee-For-Service, the Average Sales Price (ASP) payment methodology may limit competition by paying physicians the same plus 6 percent add-on payment for either the innovator or the biosimilar product, which does not encourage providers to prescribe the biosimilar.

5. *Consumer Out-of-Pocket Costs*: Within Medicare Part D, the current benefit structure results in beneficiaries paying substantially more out-of-pocket for biosimilars relative to the innovator product.<sup>30</sup>

#### MARKET-DRIVEN INTERVENTIONS

As payers strive to link payment to value, healthcare stakeholders must agree on how to define and measure the value of any given product or service. In 2015, a series of new public-facing value frameworks emerged to address this question—attempts to balance clinical benefits of a given product against the system-wide costs. Many of these frameworks failed to adequately consider patient preferences in their assessments.

In 2017, Avalere and *FasterCures* launched the Patient-Perspective Value Framework that assesses the benefits and costs of different healthcare options in the context of patients' personal goals and preferences, including things like symptom relief, complexity of regimen, and cost to the patient's family. This sort of holistic assessment of value that is broader than clinical outcomes and customized to reflect individual patient perspectives will be crucial for continuing to evolve our drug payment and delivery system to reward value.

Importantly, assessments of value should consider not only cost of the medication but total cost of care, including pharmacy and medical spending. Unfortunately, in many instances, public program structures, contractual relationships, and data limitations prevent effective assessments of value based on total cost of care. For instance, the Medicare Part D program is inherently structured to encourage lower, more competitive premiums for drugs by reducing pharmacy benefit spending—even if higher spending on medications could reduce costs in Medicare Parts A and B.

Outcomes-based contracts also represent a significant opportunity to shift away from prescription drug list prices toward value-based reimbursement models. A recent survey conducted by Avalere found that 70 percent of health plans have favorable attitudes toward outcomes-based contracts, and one-half of health plans indicate they have outcomes-based contracts already in place or are actively negotiating them.<sup>31</sup> Unfortunately, existing regulatory barriers, including standards related to government price reporting and the Anti-Kickback Statute, presently hamper further development of this trend.<sup>32</sup>

Effective outcomes-based contracts require next-generation data analysis and interventions that enable payers and manufacturers to identify patients eligible for treatment, target outreach to ensure appropriate adherence and quality improvement, and measure product performance against pre-agreed-upon outcomes on an ongoing basis. Consumer benefit can be substantially enhanced through data-based engagement around pharmaceuticals, including:

<sup>29</sup> DiMasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen. "Innovation in the pharmaceutical industry: New estimates of R&D costs." *Journal of Health Economics* 47 (2016): 20–33. Federal Trade Commission. Emerging health care issues: Follow-on biologic drug competition. June 2009 Report. Available at: <http://www.ftc.gov/os/2009/06/P083901biologicsreport.pdf>.

<sup>30</sup> Avalere Health. "Patient Out-of-Pocket Costs for Biosimilars in Medicare Part D". Avalere Health, April 2016. Web. 19 May 2017. Available at: [http://go.avalere.com/acton/attachment/12909/f02c0/1/-/-/-/20160412\\_Patient%20OOP%20for%20Biosimilars%20in%20Part%20D.pdf](http://go.avalere.com/acton/attachment/12909/f02c0/1/-/-/-/20160412_Patient%20OOP%20for%20Biosimilars%20in%20Part%20D.pdf).

<sup>31</sup> Avalere Health, "Health Plans are Actively Exploring Outcomes-Based Contracts," May 30, 2017, <http://avalere.com/expertise/life-sciences/insights/health-plans-are-actively-exploring-outcomes-based-contracts>.

<sup>32</sup> Eli Lilly and Company and Anthem, "Promoting Value-Based Contracting Arrangements," January 2016, <https://lillypad.lilly.com/WP/wp-content/uploads/LillyAnthemWP2.pdf>.

1. *Data Aggregation and Management:* Facilitating data sharing between a health plan and manufacturer to enable real-time contract management and ongoing evaluation of results.

2. *Patient Identification:* Designing algorithms to proactively identify patients most likely to benefit from a given therapy based on their demographics, geography, treatment type, and insurance coverage. Conducting statistical modeling to predict patient outcomes and potential benefit from the product.

3. *Patient and Provider Engagement:* Conduct targeted outreach to providers and directly to patients with interventions intended to improve adherence and achieve desired outcomes.

As more manufacturers and health plans embark on these data-driven partnerships, the market will evolve away from historical pricing models and toward new, innovative ways to reward outcomes.

#### CONCLUSION

The focus of this testimony is how the healthcare delivery system affects the pharmaceutical prices faced by consumers. Consumer exposure to drug costs is determined by benefit design, the competitiveness of drug classes, and approaches to provider payment. As benefit design evolves, deductibles and cost sharing for medications have increased across government and commercial payers, increasing out-of-pocket spending. Of course, consumer costs are also importantly determined by the pricing decisions made by pharmaceutical companies prior to entry of product into the supply chain, and the level and type of rebates and discounts granted.

Active management of the pharmaceutical benefit is vital to establishing a competitive pricing dynamic and achieving optimal patient outcomes. However, it is critical to ensure that benefit designs are achieving their promise, and not effectively serving as barriers to good medical and cost management. The value of pharmaceuticals should always be assessed in the context of total medical costs, and unfortunately, many government programs and employer benefit strategies fail to integrate the pharmaceutical expense line into the context of overall medical management.

Increased competition in the pharmaceutical markets holds promise for substantially reducing costs. Speeding the approval of the second- and third-branded drugs in a therapeutic class would expedite competition and lead to more rapid price concessions. Ensuring a continued robust market for generic pharmaceuticals is vital for effective cost management and improvement of population health outcomes. Finally, there is strong potential for consumers in growing biosimilar competition.

Health system change is increasingly assigning value to improvements in population outcomes for common medical conditions, and many of these outcomes can be effectively achieved through better use of medication. A patient-oriented perspective on value is key to ensuring that the American healthcare system continues to evolve toward the consumer. Further alignment of stakeholder interests around the use of pharmaceuticals holds promise to benefit consumers as payment systems evolve toward value-based design.

THE CHAIRMAN. Thank you, Mr. Mendelson. Mr. Coukell, welcome.

#### STATEMENT OF ALLAN COUKELL, SENIOR DIRECTOR, HEALTH PROGRAMS, THE PEW CHARITABLE TRUSTS, WASHINGTON, DC

Mr. COUKELL. Thank you, Chairman Alexander, Senator Murray, and members of the committee, for holding this important hearing.

Drugs are the fastest growing segment of healthcare spending and are projected to remain so. Indeed, net spending on pharmaceuticals increased 42 percent over the past decade and more than two-thirds of that was in the last 3 years.

This creates a challenge for individual patients who face high out-of-pocket costs and three-quarters of Americans say that drug prices are unreasonable. It also represents a challenge for any individual or business that pays taxes or insurance premiums which cover most of the cost of drugs.

The best way to establish prices is usually a free and competitive market, but the market for drugs is complex and deeply influenced

by public policy. Effective competition is limited in a number of ways.

For example, new drugs and some older drugs have monopoly pricing power or lack competition. There are misaligned incentives at many points in the system and historically, we have paid for new therapies, whatever the cost and however modest the benefit.

Before I get to policy options, I would like to spend a moment on the main drivers of drug spending.

The upward trend is largely the result of the rising cost of new medicines, especially high-cost biologics or specialty drugs. These are used by only 1 or 2 percent of the population, but account for more than 40 percent of costs.

Launch prices for new drugs are at unprecedented levels and year-on-year increases in brand drug prices fuel further growth. In contrast, generic drugs create significant savings despite sharp increases in the price of some individual generic products.

Generic competition has long been the main tool used to manage drug spending in the United States. When there is no competing product, the FDA prioritizes its review of new generics, but there are factors that delay generic entry in some cases, including the misuse of REMS programs and reverse payment or pay-for-delay agreements, both factors that Congress could address.

As I have noted, the main driver of spending growth is biologic drugs where Congress has granted 12 years of monopoly protection. That is more than double the 5 years of protection typical for a small molecule drug.

Another consideration is the increasing share of high-priced drugs that come to market with taxpayer subsidies and other benefits through the Orphan Drug Act. It is important to support the development of products for rare diseases, but Congress may wish to ensure that the program does not have unintended costs when the drugs are used in larger populations than the Act originally considered.

For drugs that do not have generic competition, but where there are multiple competing products that meet a similar clinical need, here there are tools that are widely used in commercial insurance, but are absent from some public programs, especially Medicare Part B.

For example, Part B lacks a formulary and any process for utilization management or prior authorization. Indeed, Part B is designed in such a way that physicians and other providers receive greater reimbursement when they choose higher priced drugs over lower cost alternatives.

Similarly, in Medicare Part D, there are a number of situations where plans are required to cover every drug in a class, such as antidepressants, and this reduces the Plan's leverage to negotiate prices.

Most of our national drug spend accrues to drug manufacturers. Estimates vary and we do not have great numbers, but at least 70 percent. Several other entities including pharmacy benefits managers, pharmacies, and wholesalers also each retain a share.

The crucial question for a self-insured employer or a plan sponsor is whether they could possibly obtain lower cost if the PBM's cut were smaller. This is a matter that largely sits in the negotia-

tions between private parties, but it is a question that Congress could address as it pertains to public programs such as Part D.

Finally, let me turn to the issue of value. Fundamentally, the debate about drug prices is a debate about value. Is the cost of the drug justified by the clinical outcomes that it produces? Value-based or outcomes-based contracts between manufacturers and purchasers are an attempt to formalize this understanding and sometimes to tie the level of payment directly to the results achieved.

Such agreements may play an important role for some products, though to date, they remain relatively rare and their effect on healthcare costs has been limited. They are unlikely to become ubiquitous in the future, not least because they are costly to negotiate and monitor.

In the larger sense, however, better alignment around value is needed. We should take into account health benefits that do not show up in the drug budget, but also recognize that the market only works when the potential purchaser has the ability to decide not to cover drugs when the cost is not justified.

We live at a time of exciting biomedical innovation. We owe it to patients and taxpayers to ensure that the cost of drugs is sustainable into the future.

Thank you and I welcome your questions.

[The prepared statement of Mr. Coukell follows:]

#### PREPARED STATEMENT OF ALLAN COUKELL

##### SUMMARY

Net spending on pharmaceuticals has increased 42 percent since 2006, with more than two-thirds of that growth occurring since 2013. Indeed, prescription drug spending is now the fastest growing share of health spending, and projected to remain so. This creates challenges for patients, who face high out-of-pocket costs, as well as American taxpayers and businesses, which pay the bulk of the cost of drugs through taxes and insurance premiums.

The main driver of increased drug spending is the rising cost of new medicines, particularly high-cost specialty products used by a small share of the population, but which account for more than 40 percent of spending. As more and more innovative medicines come to market, the growth in launch prices and the growing share of the population that could potentially rely on these products looks unsustainable.

Rising drug spending is a challenge for policymakers. While a competitive market is generally the best way to establish prices, the market for drugs is complex and deeply influenced by public policy, and effective competition is limited in a number of ways.

Potential policy responses to address drug spending include:

- Increasing competition from generic and biosimilar products,
- Increasing competition among existing drugs,
- Incorporating the value into coverage and payment decisions, and
- Improving transparency in drug benefit contracting.

As Congress seeks to manage the challenge of rising drug spending, it should look at the range of challenges and policy solutions to achieve a balance between access to innovative medicines and the equally important need to constrain cost-growth in health care.

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Chairman Alexander, Ranking Member Murray, members of the committee, thank you for holding this hearing and for the opportunity to present testimony.

I direct health programs at The Pew Charitable Trusts, a nonprofit, nonpartisan research and policy organization. One of our focus areas is the challenge of rising drug spending.

Net spending on pharmaceuticals has increased 42 percent since 2006, with more than two-thirds of that growth occurring since 2013.<sup>1</sup> Indeed, prescription drug spending is now the fastest growing share of health spending, and projected to remain so.<sup>2</sup> Currently pharmaceuticals account for 16.7 percent of total expenditures.<sup>3</sup> This creates challenges for:

- Individual patients, who face high out-of-pocket costs. Surveys show that three-quarters of Americans think drug prices are unreasonable.<sup>4</sup>
- American taxpayers and businesses, which pay the bulk of the cost of drugs through taxes and insurance premiums.

Rising drug spending is a challenge for policymakers, too, because while a competitive market is generally the best way to establish prices, the market for drugs is complex and deeply influenced by public policy, and effective competition is limited in a number of ways. These include:

- Monopoly pricing for new drugs,
- Lack of competition for some older drugs,
- Misaligned incentives and incomplete information for stakeholders, including payers, providers and patients at many points in the system, and
- A historical willingness to cover new therapies without ensuring that their clinical benefits justify the price.

In discussing potential policy options, it is important to understand the main drivers of increased drug spending. This trend is largely the result of the rising cost of new medicines, particularly high-cost specialty products (including biologics),<sup>5</sup> which are only used by a small share of the population, but account for more than 40 percent of drug spending.<sup>6</sup> Today, fewer than 2 percent of prescriptions account for over one-third of retail drug spending.<sup>7</sup> Some of these products are exciting therapeutic advances—true breakthroughs—but some are not. And they are reaching market at ever-higher launch prices. Net prices (i.e., prices after rebates) are also increasing. These products will typically not face generic competition for years. Increased volume of sales and year-on-year price increases for brand drugs that do not face competition are also a driver of spending. As more and more innovative medicines come to market, the growth in launch prices and the growing share of the population that could potentially rely on these products looks unsustainable.

While new brand drugs drive spending growth, generic drugs create significant savings. In 2016, about 90 percent of prescriptions dispensed were for generics, but total spending on these medications actually fell,<sup>8</sup> despite sharp increases in the prices of some individual products.

Net pharmaceutical manufacturer revenue from U.S. sales reached \$323 billion in 2016.<sup>9</sup> This represents the large majority, but not the total of U.S. drug spending,

<sup>1</sup> QuintilesIMS Institute, “Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021,” May 2017, Available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>.

<sup>2</sup> The Centers for Medicare & Medicaid Services projects that prescription drug spending growth will continue to outpace overall health care cost increases over the next decade. Source: Centers for Medicare & Medicaid Services, “National Health Expenditure Projections 2016–2025,” Available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf>.

<sup>3</sup> Health and Human Services Assistant Secretary for Planning and Evaluation, “Observations on Trends in Prescription Drug Spending,” March, 2016, Available at: <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>.

<sup>4</sup> Kaiser Family Foundation, “Kaiser Health Tracking Poll: September 2016,” September 2016, Available at: <http://kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/>.

<sup>5</sup> Examples include medicines for cancer, multiple sclerosis, and autoimmune conditions.

<sup>6</sup> QuintilesIMS Institute, “Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021,” May 2017, Available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>.

<sup>7</sup> QuintilesIMS Institute, “Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021,” May 2017, Available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>.

<sup>8</sup> QuintilesIMS Institute, “Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021,” May 2017, Available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>.

<sup>9</sup> QuintilesIMS Institute, “Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021,” May 2017, Available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>.

because other entities, including pharmacy benefit managers, wholesalers and pharmacies, also each retain a portion of total spending on drugs.

#### POTENTIAL POLICY RESPONSES

##### *Increased Competition From Generic and Biosimilar Products*

Competition from generic drugs has long been the main tool used to manage drug spending in the United States.<sup>10</sup> Currently, the FDA prioritizes the review of first generics, as well as generic applications for drugs for which there is only one manufacturer;<sup>11</sup> however, other policy responses could facilitate generic entry, including:

- Policies to ensure that manufacturers of brand name drugs cannot block generic developers' access to sample products required for bioequivalence testing,<sup>12</sup> and
- Policies to limit so-called "reverse payment" settlements that can, in some cases, be anti-competitive by delaying generic market entry.<sup>13</sup>

However, the agency alone cannot address the challenge of escalating drug costs. In particular, it should be noted that biologic drugs are one of the most significant drivers of increased spending and they represent 9 of the 10 highest expenditure products in Medicare Part B.<sup>14</sup> Any policy that hastens access to biosimilars and increases competition among these products would reduce spending.<sup>15</sup> This includes better aligning biologic and small-molecule exclusivity periods. Congress gave new biologics 12 years of monopoly, free of competition from biosimilars, which is more than double the 5 years of protection typically granted to new small molecule drugs.

In addition, an increasing share of drugs comes to market with the benefit of taxpayer subsidies and other benefits established through the Orphan Drug Act (ODA). While important to incentivize the development of products for rare diseases, in some circumstances, these products are used much more widely than the ODA in-

<sup>10</sup>Generics are now nearly 90 percent of all prescriptions filled, but less than 30 percent of drug spending. QuintilesIMS Institute, "Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021," May 2017, Available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>.

<sup>11</sup>FDA Center for Drug Evaluation and Research, Manual of Policies and Procedures 5240.3. Rev 2. Prioritization of the Review of Original ANDAs, Amendments, and Supplements, 2016, <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf>.

<sup>12</sup>Barriers to generic entry exist when brand drug manufacturers prevent generic companies from obtaining their products in order to carry out the testing necessary to develop a generic version of a drug. In some cases, FDA orders a manufacturer to develop a program to ensure safe use of a high-risk product, such as a requirement that a drug can only be acquired through select providers, or the manufacturer may independently opt for a restricted distribution network. However, some generic manufacturers allege that these provisions are used to restrict generic company access. Litigation to obtain samples for comparative testing often takes years to conclude. Source: The Pew Charitable Trusts, "Policy Proposal: Improving Generic and Biosimilar Developer Access to Brand Pharmaceutical Samples," May 2017, Available at: <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2017/05/policy-proposal-improving-generic-and-biosimilar-developer-access-to-brand-pharmaceutical-samples>.

<sup>13</sup>Brand and generic companies frequently strike "reverse payment" or "pay-for-delay" settlements that involve a brand pharmaceutical manufacturer paying one or more potential generic competitors to resolve patent infringement lawsuits and agree upon a date by which the generic product can come to market. Both the brand and generic company benefit under such agreements, while the public pays higher prices than it would if the generic is available sooner. In 2015, for example, the Federal Trade Commission (FTC) reached a \$1.2 billion settlement with Cephalon, Inc. for illegally blocking generic competition to its blockbuster sleep-disorder drug Provigil, driving up costs for consumers, insurers, and pharmacies. FTC and the Congressional Budget Office have estimated that banning or otherwise limiting these agreements would generate significant savings for consumers and taxpayers. However, any policy should also consider that some such settlements may be pro-competitive.

<sup>14</sup>Medicare Payment Advisory Commission, "Report to the Congress, Medicare and the Health Care Delivery System," June 2016, Available at: <http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-Medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0>.

<sup>15</sup>There is a substantial difference in the duration of market protection provided to makers of biological drugs, which are derived from living cells, and that given traditional pharmaceuticals. Reducing the period of guaranteed exclusivity for biologics from the current 12 years to 7 years would bring them more in line with traditional drugs. Such a change could generate more than \$4 billion in savings to Medicare and other Federal health care programs over 10 years. Source: Kaiser Family Foundation, "Summary of Medicare Provisions in the President's Budget for Fiscal Year 2016," February 2015, Available at: <http://kff.org/Medicare/issue-brief/summary-of-Medicare-provisions-in-the-presidents-budget-for-fiscal-year-2016/>.

tended.<sup>16</sup> Congress may wish to evaluate a number of policy options to ensure the appropriate balance, including:

- Limiting the 340B carve-out for products with an orphan designation, and
- Considering the potential to cap the value of public subsidies.

#### *Increased Competition Among Existing Drugs*

In cases where there are multiple competing, but non-identical brand drugs on the market, there are a range of tools that payers can use to manage spending while protecting patient access. These include formulary placement, prior authorization, and step therapy. While these approaches are well-established in commercial insurance, they are absent or limited in parts of the Medicare program. For example, reimbursement policies in Medicare Part B, which pays for the use of physician-administered drugs, creates a financial incentive for clinicians to choose high-priced drugs over lower cost alternatives of similar effectiveness.<sup>17</sup> In Medicare Part D, the private plans that administer the outpatient prescription drug benefit are required to cover all drugs on the market in six protected classes.<sup>18</sup> This mandate limits the ability of Part D plans to negotiate discounts for drugs in these classes. To increase competition among existing drugs in Medicare, consideration could be given to policies that would:

- Increase competition within the Medicare Part B program,<sup>19</sup>
- Increase competition within Medicare Part D,<sup>20</sup> and
- Shift some drugs from the medical to the pharmacy benefit.

#### *An Increased Focus on Value*

Value-based or outcomes-based contracts (OBCs) between manufacturers and purchasers—contracts that tie the price of a drug to specified outcomes—may play an important role for some products, though their impact on health care costs has been limited to date. A recent survey of 45 health plans found that 24 percent of them have an outcomes-based contract in place today, and an additional 30 percent are in negotiations to enter into one.<sup>21</sup> However, just one-third of plans with an OBC in place reported cost savings. There are numerous challenges in setting up these contracts, and their utility may be limited by their cost to negotiate and the need for sophisticated data systems to monitor success.<sup>22</sup> However, policymakers could examine to what extent Federal law or regulations pose potential barriers for establishing OBCs. For example, the Centers for Medicare & Medicaid Services could consider whether Medicaid Best Price rules may impede these agreements and develop additional guidance, if warranted.

Nevertheless, policymakers should consider additional strategies to incorporate the value of a drug into coverage and payment decisions. Factoring value into cov-

<sup>16</sup> Daniel MG, Pawlik TM, Fader AN, et al. The Orphan Drug Act: Restoring the Mission to Rare Diseases. *Am J Clin Oncol*. 2016 Apr;39(2):210–3.

<sup>17</sup> Health and Human Services Assistant Secretary for Planning and Evaluation, “Medicare Part B Drugs: Pricing and Incentives,” March 2016, Available at: <https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf>.

<sup>18</sup> Current law requires Medicare drug plans to cover every medication within six broad classes, including antidepressants and antipsychotics. Giving greater flexibility to private Part D plans in how they design their drug benefits could improve their ability to negotiate lower drug prices on behalf of Medicare beneficiaries and the Federal Government. Source: Lee T, Gluck A, Curfman G, “The Politics of Medicare And Drug-Price Negotiation (Updated),” *Health Affairs Blog*, September 19, 2016, Available at: <http://healthaffairs.org/blog/2016/09/19/the-politics-of-Medicare-and-drug-price-negotiation/>.

<sup>19</sup> The Medicare Part B program spends some \$25 billion each year for drugs administered in clinics and physician offices. Policies to manage biosimilar drugs similar to the current approach for generics could create greater competition. Source: The Pew Charitable Trusts, “Can Biosimilar Drugs Lower Medicare Part B Drug Spending?” January 2017, Available at: <http://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2017/01/can-biosimilar-drugs-lower-Medicare-part-b-drug-spending>.

<sup>20</sup> Medicare price negotiation (which is currently prohibited by statute) would achieve savings only if combined with new authority for Medicare to design its own formulary or preferred drug list, similar to how private plans prioritize certain drugs among equally effective therapies. Source: Shih C, Schwartz J, Coukell A, “How Would Government Negotiation of Medicare Part B Drug Prices Work?,” *Health Affairs Blog*, February 1, 2016, <http://healthaffairs.org/blog/2016/02/01/how-would-government-negotiation-of-Medicare-part-b-drug-prices-work/>.

<sup>21</sup> Avalere, “Health Plans Are Actively Exploring Outcomes-Based Contracts,” Available at: <http://avalere.com/expertise/life-sciences/insights/health-plans-are-actively-exploring-outcomes-based-contracts>.

<sup>22</sup> Garrison LP, Carlson JJ, Bajaj PS, et al. “Private Sector Risk-Sharing Agreements in the United States: Trends, Barriers, and Prospects.” *American Journal of Managed Care*, September 2015, Available at: <http://www.ajmc.com/journals/issue/2015/2015-vol21-n9/Private-Sector-Risk-Sharing-Agreements-in-the-United-States-Trends-Barriers-and-Prospects>.

erage decisions—including the choice not to cover drugs whose cost is not justified—would help reduce overpayment for marginal clinical gains. Alternatively, policies to limit the price of drugs based on assessments of their value when comparable alternative therapies exist are strategies that have the potential to lower spending on pharmaceuticals in public programs.

*Opportunities To Improve Transparency in Drug Benefit Contracting*

Pharmacy benefits managers—the intermediaries that insurers and employers pay to both administer prescription drug benefits and negotiate discounts from drug companies—play a crucial role, using their large sales volumes and their ability to create formularies to spur drug manufacturers to offer price concessions. However, a share of the savings accrues to the pharmacy benefit managers themselves, and their contracts can be extremely complex, making it difficult even for sophisticated benefits administrators to determine whether they have achieved optimal savings.

Congress could consider requiring greater transparency of contract terminology and definitions between payers and pharmacy-benefit managers,<sup>23</sup> as well as mandating the ability for payers to audit these deals, and ensuring that entities that advise purchasers on PBM contracts do not also have financial relationships with the PBMs themselves.

CONCLUSION

As Congress seeks to manage the challenge of rising drug spending, it should look at the range of challenges and policy solutions to achieve a balance between access to innovative medicines and the equally important need to constrain cost-growth in health care. I thank you for holding this hearing, and welcome your questions.

The CHAIRMAN. Thank you, Mr. Coukell.  
Dr. Howard, welcome.

**STATEMENT OF PAUL HOWARD, Ph.D., DIRECTOR AND SENIOR FELLOW, HEALTH POLICY, MANHATTAN INSTITUTE, NEW YORK, NY**

Mr. HOWARD. Thank you.

Chairman Alexander, Ranking Member Murray, members of the committee.

I would like to thank you for the opportunity to testify today about, “The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay.”

I am truly honored to be speaking to you as part of such a distinguished panel.

My testimony today is derived from my research and experience as director of health policy and a member of the Manhattan Institute’s Project FDA.

I believe our focus in this area should try to achieve three goals. To broadly promote innovation for the American patient; to reduce rent-seeking in the drug delivery system, and realign provider incentives to match the best treatment to the most appropriate patient; and finally, to continue our broad shift of reimbursement away from volume and toward value.

The United States has become the unquestioned global leader in medical innovation over the last several decades thanks to a virtual cycle of innovation where older generic drugs compete very effectively with branded drugs once those patents expire.

Inexpensive generic competition—accounting for close to 90 percent of retail drugs sold in the United States—forces branded com-

<sup>23</sup> More than two dozen of the largest U.S. corporations, including American Express, Coca-Cola, IBM, Marriott, and Verizon, have proposed greater transparency in these contracts. Source: Silverman E, “The ‘gouge factor’: Big companies want transparency in drug price negotiations,” *STAT News*, August 2, 2016. Available at: <https://www.statnews.com/pharmalot/2016/08/02/drug-price-transparency-pharmacy-benefits-manager/>.

panies to press the frontiers of science and innovation, and develop new medicines that can offset other components of healthcare spending including unnecessary hospitalizations, physician visits, and nursing home use.

Innovation benefits patients by extending and improving health, but it also benefits the economy by creating more jobs and attracting more investment to the United States. This is a social and economic contract that has worked remarkably well for the most part. In fact, it is no exaggeration to say that we stand on the precipice of a Golden Age of medicine.

New treatments could allow us to attack diseases at the molecular and genetic roots. We can finally begin to speak of lasting remissions, sharply reduced disability, and even true cures for once dreaded diseases like cancer. Even more powerful approaches, like regenerative medicine and gene therapy will undoubtedly be approved by the FDA over the next 5 to 10 years.

The outlook for innovation has never been brighter even as the industry is embroiled in a wave of product pricing controversies.

However, while most prescriptions in the United States are broadly affordable—in fact about 30 percent of all prescriptions have \$0 co-pays—there are real challenges facing patients, particularly patients with serious, chronic illnesses who are facing too much cost sharing from benefit designs through high co-insurance and deductibles, largely for what are called specialty medicines.

This is a serious challenge that must be addressed. High out-of-pocket costs can lead to lower patient compliance, increased financial stress, worse health outcomes, and even higher costs overall.

Without abandoning the current market-based paradigm, we do need to update it to meet the challenges of the 21st century and to take full advantage of new technological tools that can enable us to more rapidly match the right patient to the right medicine at the right time and at an affordable price for both patients and society.

I have three specific recommendations for Congress today.

First, reduce rent-seeking in the drug delivery system. This effort should begin with fixing the 340B Drug Discount Program. 340B drug sales have become a major source of hospital revenues and account for as much as 50 percent of infused oncology products.

The shift of treatments into the 340B environment has increased the cost of cancer medicines, increased the cost of treatment for patients with both commercial insurance and Medicare Part B co-insurance, and has changed the mix of treatments toward more expensive therapies.

Congress should reform 340B and return it to its original intent to assist hospitals that largely serve indigent and uninsured populations, and ensure that its rebates are extended to the most vulnerable patients, like the uninsured.

Second, we should promote value-based arrangements that give innovative companies, physicians, and hospitals equal skin in the game to match patients to treatments that work. Regulators can help accelerate the transition to these contracts by removing regulatory barriers that discourage companies from testing the full potential of indication and outcomes-based contracts to improve pa-

tient outcomes and match the performance of medicines to their real world outcomes.

Finally, I would encourage Congress to consider a broader menu of reforms that would allow payers to take a longer term view of the value and costs of new medicines. Such reforms would include encouraging the uptake of value-based designs within high deductible health plans; new financing tools for State Medicaid programs that would allow them to purchase curative technologies like Hepatitis C drugs upfront, but spread the costs over longer periods of time; and multiyear private insurance contracts that may align payers' incentives with patients' long term health.

In conclusion, for the last 30 years, the United States has benefited from arrangements that have put us on the cusp of tremendous new medical achievements. The system is under strain today because the pace of the innovation is accelerating while our healthcare system is still divided into payment silos that create the appearance of a zero sum game between stakeholders.

I am confident that policymakers can work together on a bipartisan basis to update and improve America's virtual cycle of innovation and affordability for the next 30 years.

Thank you.

[The prepared statement of Dr. Howard follows:]

PREPARED STATEMENT OF PAUL HOWARD, PH.D.

#### SUMMARY

An effective balance between strong upfront patent rights and rapid generic competition has helped make the United States the unquestioned global leader in medical innovation, while also assuring broad affordability, for the last several decades. However, there are real challenges facing the health care system today, specifically for patients with serious chronic illnesses who face high coinsurance or deductibles.

The U.S. health care system is in dire need of competition to reduce wasteful and ineffective care. However, addressing drug prices directly, in a silo, is inadvisable because we want technology to substitute for labor, something that happens only through innovation.

The Centers for Medicare and Medicaid Services (CMS) expects that medicine's share of total health care costs will closely track overall health care spending growth over the next decade. However, costs attributable to expensive specialty medicines are rising significantly faster than for traditional drugs, with the result that a small fraction of all prescriptions account for a disproportionate share of all out-of-pocket spending on prescription medicines.

Fortunately, there are promising signs that payers and manufacturers are edging toward agreement that patients with serious diseases facing coinsurance should have access to PBM-negotiated discounts. There is also growing agreement that contracts for high-cost, high-value medicines should reflect evidence of their real-world performance.

Congress, CMS, and FDA have important roles to play in encouraging the market to shift to new arrangements that lower barriers to patient access.

First, Congress should reform the 340B program and return it to its original intent to assist hospitals serving largely indigent and uninsured populations. The current system instead encourages profit skimming and hospital consolidation.

Second, HHS and FDA should coordinate on creating safe harbors from Federal regulations that would allow stakeholders to experiment with new contractual arrangements. This allows manufacturers to bear financial risk for new medicines, without discouraging innovation.

Finally, Congress should consider opportunities to encourage using value-based insurance designs, new financing tools for State Medicaid programs, and longer-term insurance contracts that better align payers' incentives with patients' long-term health.

Chairman Alexander, Ranking Member Murray, members of the committee, I would like to thank you for the opportunity to testify today about “The Cost of Prescription Drugs: How the Delivery System Affects What Patients Pay.” I am truly honored to be speaking to you today.

Bipartisan support for medical innovation, including strong support for FDA user fee agreements, an encouraging environment for translating basic medical research into promising new treatments, and an effective balance between strong upfront patent rights and rapid generic competition once those patents expire has made the United States the unquestioned global leader in medical innovation for the last several decades.<sup>1</sup>

Broadly speaking, robust generic competition, along with the advent of large and sophisticated payers, has kept the relative share of health care costs attributable to medicines broadly stable, even as new medicines have become a cornerstone of treatment for acute and chronic illness.<sup>2</sup>

However, there are real challenges facing the health care system today, specifically for patients with serious chronic illnesses who are facing high coinsurance or deductibles largely for what are called “specialty” medicines, and that challenge needs to be addressed.

Ironically, part of that challenge is due to the advent of highly effective new treatments for hepatitis C, cystic fibrosis, some cancers, and rheumatoid arthritis. A wave of even more powerful treatments, including gene therapies, new immunoncology therapies, and regenerative medicine approaches are already on the horizon and likely to be approved by the FDA over the next 5 to 10 years. The outlook for innovation has never been brighter, even as the industry has become a lightning rod for product pricing controversies.<sup>3</sup>

I would remind critics that having too many effective therapies is an enviable problem to have, and can largely be addressed by enhancing market competition and creating new financing and reimbursement tools that allow payments for treatments to be pegged to their real-world outcomes—like lowering costs elsewhere in the health care system, improving patient survival or quality of life, or simply delivering a comparable outcome to existing technologies less expensively.<sup>4</sup>

The U.S. health care system is in dire need of competition to reduce wasteful and ineffective care, and new technological platforms can allow the rapid analysis of large volumes of patient data—enabling competition not only between medicines, but among providers and different payment platforms. In short, Congress should create incentives that reward providers who use medicines (both generic and branded) and technology to deliver care as efficiently as possible, while also empowering patients with the information they need to identify high quality providers.<sup>5</sup>

Fixing drug prices in a silo is inadvisable because we want technology to substitute for labor, including unnecessary hospitalizations, doctor’s visits, or debilitating stays in a nursing home.<sup>6</sup> Bending the curve of health care cost growth and

<sup>1</sup>For a fuller discussion, see Biopharmaceutical Policy for American Leadership 52 in the 21st Century, Peter Huber & Paul Howard. [https://nationalaffairs.com/storage/app/uploads/public/dclib/20161209\\_UnleashingOpportunityInnovationPolicyBooklet.pdf](https://nationalaffairs.com/storage/app/uploads/public/dclib/20161209_UnleashingOpportunityInnovationPolicyBooklet.pdf).

<sup>2</sup>Total U.S. health care spending in 2015 was \$3.2 trillion. Approximately two-thirds of those costs are attributable to hospital care (roughly 30 percent) and physician services (around 25 percent). Outpatient prescription drug spending has held steady at around 10 percent of total expenditures for decades. Adding in hospital administered drugs raises that share to 14–15 percent. Fein, Adam J., *The 2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*, Drug Channels Institute, 2017.

<sup>3</sup>Many critics point to European drug price controls as the solution—ignoring the outsized role that the U.S. market plays in global innovation generally. See To Lower Drug Prices, Innovate, Don’t Regulate. <https://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/to-lower-drug-prices-innovate-dont-regulate>.

<sup>4</sup>For a fuller discussion of the role of analytics, diagnostics, and outcomes-based payments see Precision Medicine in the Era of Health Care Reform. <https://www.manhattan-institute.org/sites/default/files/R-PH-0416.pdf>.

<sup>5</sup>As researchers in a Health Affairs blog wrote in 2015:

Adherence to treatment guidelines and quality remain highly variable across providers in a wide variety of oncology domains, including end-of-life care, prostate cancer, ovarian cancer, and colorectal cancer screening.

Problems range from underuse of highly effective therapies and procedures to overuse of ineffective ones. Thus, while today’s typical cancer patient is likely better off than her counterpart from earlier years, not all patients are receiving the most effective care. . . . Rewarding physicians for patient health improvement moves physician incentives closer to the values and needs of patients.

<sup>6</sup>See Michael Mandel, Rising Labor Costs Accounted for 47 percent of Increased Personal Health Care Spending in 2015. <http://www.progressivepolicy.org/blog/rising-labor-costs-accounted-47-percent-increased-personal-health-care-spending-2015/>.

delivering state-of-the-art care can, and must, go hand in hand if we are to meet America's most pressing health care challenges.

There is no accounting or discount scheme that will enable us to grapple with the scourge of Alzheimer's short of medicines that delay, or perhaps even prevent it entirely. Innovation is our best hope for lowering costs *and* improving outcomes.

With that in mind, I would like to frame my remarks with some observations that I hope will guide our discussion today.

We stand at the precipice of a Golden Age of medicine, with new treatments that allow us to treat diseases at their molecular and genetic roots, where we can begin to speak of lasting remissions, sharply reduced disability, and even true cures—as from gene therapy.

Nonetheless, broadly speaking, the vast majority of prescriptions in the United States today are highly affordable, with roughly 30 percent having a \$0 copay. Most Americans who take prescription drugs regularly say they are affordable. In fact, close to 90 percent of all retail prescriptions in the United States today are for generics,<sup>7</sup> which have saved payers hundreds of billions of dollars over the last decade.

Apart from a sharp surge in drug spending in 2014, when a new class of highly effective medicines for hepatitis C were introduced, drug price growth has been moderate, especially when we disaggregate price increases from increased utilization. A growing number of Americans are taking medicines, which is unsurprising given that age is one of the leading risk factors for developing a chronic illness. Payers, however, have been able to leverage large purchasing networks to increase manufacturer rebates as a share of gross revenues.

As a result, the Centers for Medicare and Medicaid Services (CMS) expects that medicine's cost growth will closely track overall health care spending growth over the next decade.<sup>8</sup>

When we drill down into the market, however, costs attributable to so-called specialty medicines are rising significantly faster than for traditional drugs, and today constitute close to 30 percent of all drug revenues. Prices for these medicines are rising significantly faster than other costs, although they also treat especially serious chronic diseases. They also face less generic competition, including, at least for now, from biosimilars.

That overall drug spending has not risen faster is a testament to the success of insurers and pharmaceutical benefit managers (PBMs) cost containment strategies. They have employed utilization management tools like prior authorization, drug tiering and coinsurance, and larger deductibles for non-preferred medicines manage the uptake of specialty drugs.

To retain formulary access for specialty medicines, companies often offer quite substantial rebates. One PBM, Express Scripts, noted in the last year that it held price increases for its members to under 3 percent.

How is it possible, then, that payers can complain about a drug pricing crisis, while pharmaceutical firms note that drug spending, and especially net pricing after accounting for rebates and utilization increases, are fairly stable?

The he-said, she-said debate can be resolved by simply noting that there are an increasing number of patients with high deductible plans, where medicines are part of a single combined medical and pharmacy deductible, and of patients with traditional insurance who are prescribed medicines where they pay coinsurance based on the list prices of these medicines, and thus do not benefit from PBM-negotiated discounts.

For patients who may need a medicine that is excluded from the PBMs formulary entirely, short of manufacturers' patient assistance programs, they may have to bear the full costs of these medicines themselves. (PBMs respond that they pass along these rebates to employers and other payers, helping to keep overall health insurance increases lower than they would otherwise be.)

To summarize: Patients with serious chronic illnesses may find themselves caught between the hammer of rising cost control efforts at a time of rapid therapeutic innovation.

There are some promising signs that payers and manufacturers recognize that the status quo is unsustainable, and are edging toward agreement that patients with serious diseases should have access, at the point of purchase, to PBM-negotiated discounts.

There is also growing agreement that reimbursement contracts for high-cost, high-value medicines should reflect evidence of their real-world performance, which may

<sup>7</sup>Fein, Exhibit 2: Unbranded and Branded Generics, Share of U.S. Prescriptions, 2005–21.

<sup>8</sup>Howard and Feyman, Drug Price Controls Hurt Patients Most. <https://www.manhattan-institute.org/html/issues-2016-drug-price-controls-hurt-patients-most-7949.html>.

be very different than outcomes generated in clinical trials used for FDA approval—or for an entirely new indication, where evidence may be lacking at the time of approval.

Congress, HHS, and FDA have critical roles to play in encouraging the market to shift to new arrangements that lower barriers to patient access and encourage greater collaboration in getting the right medicine to the right patient at the right time—and at a price that is sustainable for patients, payers, and innovators.

I have three recommendations for Congress today.

- First, fix the 340B drug discount program. 340B was originally designed to assist hospitals serving indigent patients, but has expanded to cover approximately 50 percent of the market for infused oncology medicines.

While hospitals acquire these drugs at large mandatory discounts, several studies suggest that they are billing commercial insurers a percentage of allowable charges, which is significantly higher than their acquisition price. As a result, such sales have become a major source of hospital revenues and an inducement for vertical hospital consolidation—i.e., for hospitals to acquire oncology practices and then charge far higher prices than standalone oncology practices (who charge Medicare ASP+6 percent).

Commercially insured patients and Medicare Part B patients thus may find themselves paying coinsurance on these highly inflated prices. Congress should reform 340B, returning it to its original intent to assist hospitals that largely serve indigent and uninsured populations, and ensure its rebates are extended to vulnerable patients (like the uninsured), and commercially insured and Medicare Part B patients who may be treated at these hospitals and find themselves paying coinsurance. Reducing the financial arbitrage available to hospitals would also reduce the incentive for hospitals to acquire oncology practices, reduce pricing pressures on oncology payers and patients, and reduce pricing distortions in other parts of the market.

- Second, stakeholders also seem to be in broad agreement that novel reimbursement contracts should reflect medicines' value, both through indication- or outcomes-based designs. Regulators should help accelerate the transition to these contracts by removing regulatory barriers that discourage companies from testing the waters.

Specifically, HHS and FDA should coordinate on creating safe harbors from Federal regulations that would allow stakeholders to experiment with innovative new contractual arrangements. These might allow for reimbursement to track a medicine's real-world performance, or for pricing to evolve as the weight of evidence evolves.

For instance, recently Eli Lilly and Anthem petitioned HHS and the FDA to grant them safe harbor from regulations, like Medicaid Best Price and Stark anti-kickback rules, which prohibit them from experimenting with these types of contracts.

With the FDA at the table, regulators could also create standards for the collection of real-world evidence that would allow the agency to update a drug's label to reflect new information on safety and efficacy, expand to new label indications, and generally support the development of a "health care learning system." This system uses information on patient outcomes, medication regimens, and even delivery system reforms to create a rapid feedback loop that helps ensure that the right medicine reaches the right patient at the right time—and all in a framework pushing every dollar spent on patient care to be used as efficiently as possible.

- And finally, I would encourage Congress to consider a broader menu of reforms that would allow payers to take a longer perspective on the value and costs of new medicines. Such reforms would include encouraging the uptake of value-based insurance designs; new financing tools for State Medicaid programs to purchase curative technologies rapidly, but spread the costs over longer periods of time; and multi-year private insurance contracts that may align payers' incentives with patients' long-term health. Congress should also continue to empower patients with more information about both provider pricing and outcomes for specific indications—helping the market to reset on a competitive basis.

In conclusion, once we start asking questions about how to deliver better value to patients, to society, and to future generations, we are apt to look far past our current drug pricing debates—and toward the future of precision medicine.

For the last 30 years, the United States has benefited from arrangements that have put us on the cusp of tremendous new medical achievements. The system is under strain because the pace of innovation is accelerating, while our health care system is still divided into payment silos, with a short-term framework that under-values the long-term impact medicines can play in resolving our most pressing health care challenges—including cancer, major depression, diabetes, and Alzheimer's.

Rather than pointing fingers, I hope that Congress can construct arrangements that will serve patients better for the next 30 years, unleashing the full potential of precision medicine to improve and lengthen patients' lives, here and around the globe.

Thank you, and I would be happy to answer any questions you may have.

The CHAIRMAN. Thank you, Dr. Howard.

Dr. Anderson, welcome.

**STATEMENT OF GERARD ANDERSON, Ph.D., PROFESSOR OF MEDICINE, JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE, BALTIMORE, MD**

Mr. ANDERSON. Thank you, Chairman Alexander, Senator Murray, and members of the HELP committee today.

This summer, I will have the opportunity to teach 250 of our new MPH students and I am fortunate enough to have Barbara Mikulski as one of my professors in the class.

I do not receive any financial support from pharmaceutical companies, entities involved in the pharmaceutical supply chain, or health insurers.

My main concern today is that healthcare prices are limiting access to essential drugs. Innovation is absolutely wonderful, but all Americans need to be able to afford these innovative drugs.

In my written testimony, I focus on four categories of people with the most problems accessing drugs. Almost one-quarter of all Americans have a chronic condition and one-quarter of them have two or more chronic conditions. In my testimony, I talk about a woman with multiple chronic conditions with insurance who has monthly bills of \$1,700.

The second category of patients are those who are prescribed very expensive prescriptions drugs. One of my physician colleagues at Johns Hopkins came to me very upset last year. He treats babies with neuromuscular defects and was thrilled to learn that the FDA has approved a new drug to help these babies. A month later, he learned that the drug company had set the price at \$750,000 for the first year of treatment and \$375,000 in subsequent years.

Who wants to hear that your new baby has a genetic defect that will make them incompetent of doing most anything, and then to learn the drug that treats them costs \$750,000? In Baltimore, you can buy a mansion for \$750,000.

A third category is people taking off-patent drugs where the price has increased dramatically because there are no competitors. This is what Martin Shkreli did. The Senate Aging Committee, led by Senator Collins, did a wonderful report on this topic recently.

The fourth category is public programs that cannot afford to pay for drugs. We are working with Louisiana to help them find ways to fund Hepatitis C drugs for the 35,000 Louisianans with Hepatitis C. Hepatitis C is the infectious disease that kills more people than any other infectious disease including AIDS.

The drug costs over \$20,000 even with several competitors and Louisiana simply does not have the \$764 million at current prices to treat everyone with Hepatitis C.

The next part of my drug testimony discusses drug pricing. Drug pricing is exceedingly complex. I wore my tie with the writing of Leonardo da Vinci as a reminder of how complicated drug pricing

systems have become. I am not even sure Leonardo da Vinci could understand drug pricing today.

It begins, though, with a drug company setting a list price for their drug. It is important to recognize that the Government gives that branded drug company patent and market exclusivity periods. These are government-given monopolies that protect the intellectual capital of the drug company and make it profitable for the drug company to engage in research and development.

However, as any economist can tell you, when a company has a monopoly, it sets the price that maximizes its profits. The monopoly price is not the price that allows everyone to get access to the drug.

The Senate Finance Committee did a very nice report on how Gilead had set the price for their Hepatitis C drug assuming that most people would not get access to the drug.

Few people have argued that the list price is irrelevant because few people actually pay the list price. However, the list price is used to determine the amount of cost sharing that many patients pay. Thus, patients are harmed when the list price increases.

Other experts in this panel have discussed the relationships between the drug companies, the PBM's, the wholesalers, and the pharmacies. It is important to recognize, however, that the process begins with the drug company setting the price.

The last portion of my testimony discusses several options for the committee to discuss, and I only have time for two of them right now.

One is a policy that would keep people like Martin Shkreli from putting a drug into something called limited distribution chain. Limited distribution chains prevent competitors from getting access to the drug, establishing bioequivalence, submitting an ANDA to the FDA, and then competing. So it is very anti-competitive.

Most drugs are paid on a fee for service basis. Putting drugs, as some of the others have talked about, into value-based purchasing—like bundled payments and accountable care organizations—would allow the physicians to decide which drugs are necessary for the patient taking into account the cost of the drug and alternative approaches. This would fundamentally change the drug purchasing system by putting physicians, not PBM's and health insurers, in charge of the process.

I am happy to answer any questions.

[The prepared statement of Dr. Anderson follows:]

PREPARED STATEMENT OF GERARD ANDERSON, PH.D.

#### SUMMARY

High drug prices are causing access problems. Patients in four categories are having the greatest difficulty accessing drugs:

1. Patients with chronic diseases who cannot afford all of their medicines.
2. Patients prescribed very expensive specialty drugs.
3. Patients prescribed off-patent drugs whose prices have recently skyrocketed due to a lack of competition.
4. Patients on public programs where the public program cannot afford to purchase the drug.

In my written testimony, I provide examples of people in each of these situations.

## HOW DRUG PRICES ARE SET AND WHY THIS MATTERS TO PATIENTS

1. It begins with a drug company setting a list price for the drug. No regulatory or market forces constrain the list price.
2. Branded drug companies have government-issued monopolies (patents and market exclusivity periods).
3. The list price matters because it is often used to determine the amount of cost sharing that patients pay.
4. Pharmaceutical benefit managers (PBMs) earn their profits primarily by negotiating discounts off of the list price. The greater the list price, the greater the spread between the list price and the actual transaction price and the greater the profit the PBM earns. As a result, there is a financial incentive for the PBMs to try to get the drug company to increase the list price. This in turn increases the amount of cost-sharing the patient pays.
5. Wholesalers bring the drug from the manufacturer to the pharmacy or hospital and earn a small profit doing so.
6. Pharmacies and hospitals sell the drug to the patient after they negotiate a price with the drug manufacturer and add a dispensing fee.
7. Most patients pay something out-of-pocket for the drug that is based on their insurance.
8. All of this information is confidential and the patient cannot understand how the cost-sharing amounts are set.
9. Sometimes the patient would pay less if they ignored their insurance coverage and paid cash.

## POLICY RECOMMENDATIONS

Finally, I briefly present a series of recommendations about how to increase the level of competition in the supply chain for pharmaceuticals and lower pharmaceutical prices while still providing incentives for innovation.

Two policy recommendations warrant special considerations:

1. Preventing companies from putting drugs into limited distribution chains that keep generic companies from accessing the drug, testing for bioequivalence, and submitting applications to the FDA.
2. Placing drugs into value-based purchasing arrangements like bundled payments and ACOs. This is a disruptive system putting doctors in charge.

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Chairman Alexander, Ranking Member Murray and members of the HELP Committee, my name is Gerard Anderson. I am a professor at Johns Hopkins Schools of Public Health and Medicine and director of the Johns Hopkins Center for Hospital Finance and Management.

This summer, I will have the opportunity to teach our 250 entering MPH students a course on public health policy, and Senator Barbara Mikulski will be giving them a lecture based on her years of experience on the HELP committee.

I do not receive any financial support from pharmaceutical companies; entities involved in the pharmaceutical supply chain, or health insurers. I am also not testifying on behalf of Johns Hopkins University, but in my role as a professor at Johns Hopkins University.

Today, I will cover three topics.

First, my main concern about high drug prices is that they are limiting access to essential drugs. Innovation is wonderful, but people need to be able to afford the innovative drugs. I begin by showing how high drug prices are affecting access to care. I will focus on four areas where people are having the greatest difficulty accessing drugs.

1. Patients with chronic diseases who cannot afford all of their medicines.
2. Patients prescribed very expensive specialty drugs.
3. Patients prescribed off-patent drugs whose prices have recently skyrocketed due to a lack of competition.
4. Patients on public programs where the public program cannot afford to purchase the drug.

Second, I will attempt to summarize how drug prices are set and how this process can affect patients' access to these medications.

And third, I briefly present a series of recommendations for increasing the level of price competition, revising regulations and legislation, lowering pharmaceutical prices, and improving patients' access to essential drugs, while still providing healthy returns and incentives for innovation.

## HOW HIGH DRUG PRICES AFFECTS ACCESS TO CARE

While many patients have some level of difficulty paying for their drugs, patients taking a large number of drugs or very expensive drugs face an even greater health challenge.

**Almost half of all Americans have one or more chronic conditions.** Perhaps less well known is that one-quarter of all Americans have multiple chronic conditions, and there are about five million Medicare beneficiaries with five or more chronic conditions. Many of these chronic conditions require people to take multiple drugs, and having access to the drugs to treat these conditions is critical for patients to remain healthy.

The problem is that many people taking these drugs cannot afford to fill their prescriptions. As a result, they are forced to make choices between paying the rent, purchasing food, caring for their children and being able to afford the drugs that will keep their chronic illnesses from becoming even worse. A December 2016 Kaiser Family Foundation poll found that one in five Americans did not fill a prescription last year because of cost and one in six Americans cut pills in half or skip doses in the prior year. This is rationing based on price.

I am working with an organization called Patients for Affordable Drugs, an organization that has been collecting stories from over 7,000 people who are having difficulty paying their prescription drug bills. Its founder, David Mitchell, told me that the most challenging stories that he gets every day are from people with chronic conditions that cannot afford to purchase their drugs or need to split pills or skip doses in order to have the prescription last longer. High drug prices are impeding their access to essential medicines that directly affects their health.

A woman from Schenectady, NY wrote him:

“I am a 53-year-old diabetes patient who was diagnosed with bipolar disorder. I have also suffered 8 strokes in the last 20 years. As I have gotten older, controlling my blood sugar has become harder and harder. I had never had a problem paying for my daily medications until a year and a half ago. The diabetes supply that I need are [she lists five drugs] and other supplies such as a blood meter, needles, test strips, etc. Combine that with the costs of the other 10 drugs I take to control my other medical issues, co-payments, [and] hospital tests needed; I am unable to afford these increasing monthly costs. Under my Part D coverage with Medicare and Humana, my monthly supply of these drugs will cost me approximately \$1,700 monthly.”

She is one of the millions of patients who are unable to afford drugs to treat chronic conditions in spite of having health insurance coverage.

**Other patients struggle to afford their treatment because they have been prescribed an extremely expensive specialty drug.** Recently, a number of very effective new drugs have entered the market offering complete cures or ways to maintain a high level of functioning. These are the kinds of innovations that will improve health status and increase life expectancy. The problem is that many of these drugs are so expensive that most people cannot afford them.

One of my colleagues at Johns Hopkins who treats babies with genetic neuromuscular defects was thrilled when he learned that the FDA had approved the first drug to help these babies. The drug, a new molecular entity, essentially repairs the genetic defect and will allow the baby to live a normal life. The treatment is only truly effective if it is given immediately following birth before the genetic defect leads to muscular deterioration. A month later, the doctor was mortified to learn that the drug company set the price at \$750,000 for the first year of treatment, and \$375,000 per year after that for the rest of the child’s life. Who wants to hear that your newborn has a genetic defect and then learn that your young family will need to raise \$750,000 in the next 2 weeks in order for your infant to progress normally? If the insurance company initially denies the payment, then the appeal will almost always require more than 2 weeks. It is hard to imagine the stress that young families feel when faced with this situation.

The Senate Finance Committee conducted a study of the pricing of one of these specialty drugs. Gilead was the first drug company to develop a cure for hepatitis C. This was a major clinical innovation offering a cure for an infectious disease. Hepatitis C is the infectious disease responsible for the greatest number of deaths in the United States every year—even more than HIV/AIDS. However, the drug company set a price that few could afford, and Gilead did this knowing that not every one with hepatitis C would be able to afford the drug. Let me simply quote one line from the executive summary of the Senate Finance Committee’s report:

“Gilead’s own documents and correspondence show its pricing strategy was focused on maximizing revenue—even as the company’s analysis showed a lower price would allow more patients to be treated.”

While we do not have exact numbers of the percent of people with hepatitis C that have been treated, the best estimate is that less than 20 percent of people with hepatitis C have been treated for a potentially fatal, but curable infectious disease. Even after the drug has been on the market for 3 years and two additional competitors have entered the market, still less than 20 percent of hepatitis C patients have received treatment.

Apparently, simply having competition for branded drugs is not sufficient to bring the price down to a level that most people can afford. The United States should have prices that allow everyone to have access to these life saving drugs. While we need innovation, we also need access and high drug prices set by the drug companies should not ration access.

The Kaiser Family Foundation conducted a study of Medicare beneficiary cost sharing for specialty drugs. For Medicare beneficiaries with Part D coverage, out-of-pocket costs averaged \$7000 for drugs to treat hepatitis C, \$6000 for drugs to treat multiple sclerosis, \$4000 for drugs to treat rheumatoid arthritis and \$8000 for drugs to treat certain types of cancer. For a social security recipient earning \$26,000 per year, these out-of-pocket costs represent 16 percent to 32 percent of the person’s total income for the year and clearly are prohibitively expensive. At these prices, it is not surprising that many Medicare beneficiaries with Part D insurance cannot afford these drugs.

**Even for off-patent drugs, high prices can still create access problems.** Much of the recent attention has focused on the rapid increases in prices of off-patent drugs that do not have any competitors. The generic drug industry works reasonably well when there are three or more competitors selling the same drug. Since the drugs are interchangeable, competition works to keep prices affordable.

However, problems occur when there are no competitors (or even just one or two). When there is little competition for off-patent drugs, companies can raise the prices without fear that consumers will choose a lower priced competitor. This is exactly what Martin Shkreli did with his drug. He took an off-patent drug that had been on the market for many years, raised the price by 3,500 percent, and created mechanisms to prevent other competitors from entering the market.

Analysis by Senator Susan Collins and the Senate Aging Committee staff showed how Martin Shkreli and others have been able to keep competitors from entering the market.

First, the company acquired a “sole-source drug, for which there was only one manufacturer, and therefore faces no immediate competition, maintaining monopoly power over its pricing.”

Second,

“The company ensured the drug was considered the gold standard—the best drug available for the condition it treats, ensuring that physicians would continue to prescribe the drug, even if the price increased.”

Third,

“The company selected a drug that served a small market, which were not attractive to competitors and which had dependent patient populations that were too small to organize effective opposition, giving the companies more latitude on pricing.”

Fourth, the company created a closed distribution system to stifle competition. As the report notes,

“The company controlled access to the drug through a closed distribution system or specialty pharmacy where a drug could not be obtained through normal channels, or the company used another means to make it difficult for competitors to enter the market.”

Without access to the drug, a competitor cannot conduct bioequivalence studies in order to submit a drug application to the FDA. Increasingly, drug companies are using these closed distribution systems to stifle competition. This is an area that Congress could address, as I will discuss later.

The Senate Aging Committee concluded by stating,

“Lastly, the company engaged in price gouging, maximizing profits by jacking up prices as high as possible. All of the drugs investigated had been off-patent for decades, and none of the four companies had invested a penny in research and development to create or to significantly improve the drugs. Further, the committee found that the companies faced no meaningful increases in production or distribution costs.”

There have been hundreds of stories written about the problems created by these rapid price increases in off-patent drugs without competition. Let me quote from another email that Patients for Affordable Drugs received: My wife “has seen [her drug’s] price increase by over 3,600 percent since 2014.” Again, this is for an off-patent drug.

“Today her medications cost \$283,000 per year or about \$200 per dosage—from the 1980s to 2006 [drug name eliminated for confidentiality reasons] was \$1.00 per dose/\$1,500 per year.”

People simply do not have the resources to afford these drugs and often the cost sharing is prohibitively expensive.

**Finally, public programs cannot afford these expensive drugs.** States and the Federal Government have budget constraints and high prices are forcing public programs to make very difficult life or death decisions.

For example, the State of Louisiana wants to expand treatment for hepatitis C, but cannot afford to offer the care to everyone at current prices. According to the Secretary of Health in Louisiana, it would cost \$764 million at current prices to cover the 35,000 uninsured and Medicaid recipients with hepatitis C, in the State. Louisiana simply does not have these resources, without dramatically reducing spending for things like education or public safety.

We, at Johns Hopkins, are working with the Secretary of Health in Louisiana to help her develop ways so that Louisiana can afford to purchase the drugs and prevent the spread of an infectious disease. Similar concerns about the affordability of certain drugs have been expressed by other States and by Federal agencies such as the Veterans Administration and the Indian Health Service.

A woman from Alabama writes to Patients For Affordable Drugs:

“My husband and I are currently doing without needed medication because of the cost. We recently lost our health coverage. With the high cost of medication, we simply cannot afford to fill our prescriptions. My daughter is in the same position, however she is on Medicaid. She has numerous health conditions and without her needed prescriptions, which Medicaid won’t cover due to the cost, she ends up being forcibly hospitalized for treatment.”

States must make difficult choices. Simply telling them to cover everyone that needs a drug ignores the fiscal realities.

#### HOW DRUG PRICES ARE SET AND WHY THIS MATTERS TO PATIENTS

The establishment of the initial drug price, how this then gets translated into the price that the pharmacy or hospital pays to acquire the drug, and how it ultimately impacts the price that the patient pays to obtain the drug is extremely complicated. Much of the process is not transparent. My summary by necessity is an oversimplification of the process. A full description would consume a book.

It begins with a drug company setting a list price for the drug. There are no regulatory or market forces that determine the list price that the brand name drug company can set, and the drug company has full discretion and market power to set whatever list price it chooses when the drug is launched or to change the list price at any point of the life cycle of the drug.

It is important to recognize that the branded drug company has patent and market exclusivity periods that prevent other drug companies from manufacturing the drug. These are government given monopolies that protect the intellectual capital of the drug company and make it profitable for the branded drug company to engage in research and development.

However, any economist can tell you the dangers when a company has a monopoly; the drug companies are able to set the price that maximizes their profit. The monopoly price is not the price that allows everyone to get access to the drug. They set a price that is much higher than they would set in a competitive environment.

There are a number of factors that go into the drug company setting the list price. One factor is the cost of research and development. However, the list price is typically not based on the research and development that went into developing that specific drug; instead, the company looks at their entire portfolio of drugs to determine the profits they will require to create the next generation of drugs. Even using the pharmaceutical industry’s own data, it is clear that branded drug companies typically spend less than 25 percent of their revenues on research and development, and far more on advertising and marketing.

Many people have argued that the list price is irrelevant because few entities actually pay the list price. However, the list price is often used to determine the amount of cost sharing that many patients will pay. Since the list price is the only

price that is publicly announced, it becomes the basis for many cost-sharing agreements. Thus, patients are harmed when the list price goes up.

Most people with health insurance have their drug benefits determined by pharmaceutical benefit managers (PBMs), who negotiate prices with drug companies on behalf of health insurers or large employers. Only three PBMs control 80 percent of the market, which is troubling from a competitive vantage point.

Increasingly, it is being reported that PBMs are responsible for some or even most of the price increases. While they do have a role in the price increases, PBMs also serve to negotiate lower prices because of their tremendous buying power.

PBMs earn the majority of their profits by negotiating rebates off of the list price. The greater the list price, the greater the difference between the list price and the actual transaction price, and the greater the profit the PBM can earn. As a result, there is a financial incentive for the PBMs to try to get the drug company to increase the list price to show the insurance company or the large employer that they are getting a larger discount. However, this also serves to maximize the PBM's own rebates. For example, if the list price is \$100 instead of \$50, and if the actual transaction price is \$30, then the discount appears much greater when the list price is \$100. Also the PBM's rebate might be greater. Neither the size of the rebate nor the actual transaction price is transparent. Congress might want to use its subpoena power to investigate.

The fact that a higher list price can result in greater sales for the drug company is contrary to all economics principles. In nearly all markets, sales decline when prices increase. However, for drug pricing, higher list prices and the greater rebates can help drugs get better placement on the formulary and hence more sales. The challenge is to change the rebate structure for PBMs a topic that I discuss later in the testimony.

Wholesalers bring the drug from the manufacturer to the pharmacy or hospital. The profit margins of the large wholesalers add only 1–2 percent to the price of the drug.

Pharmacies and hospitals sell the drug to the patient after they negotiate a price with the drug manufacturer and add a dispensing fee. Doctors, pharmacies and hospitals can get rebates from drug companies for using their drug as well. These rebate arrangements are almost never disclosed to patients.

Most patients pay something out-of-pocket for the drug. The exact amount is based on their insurance coverage. Insurance companies and PBMs determine the price that the patient will pay out-of-pocket by placing drugs on different tiers with different levels of cost sharing. PBMs and the branded drug companies negotiate aggressively on tier placement and this also helps determine the amount of the rebate. Again, all of these negotiations are confidential and the patient cannot understand how the cost sharing amounts are set. As a result, there have been calls for greater transparency in the pharmaceutical supply chain.

What we have recently learned is that some PBMs have instituted gag clauses with the pharmacy that prevent the pharmacy from telling their patient that if the patient paid cash instead of using their insurance card the price would be lower. Placement of the drug on a cost-sharing tier where the drug has a very high list price and low transaction price could mean that paying the cost sharing based on the list price is greater than the cash price. Pharmacies have reported this occurs quite often.

However, it is important to note that it all starts with the drug company setting the list price. Brand name drug companies have complete discretion on the price that they set and can raise it at any time. The government does not determine or limit the price. In fact, the government gives the branded drug company a government issued monopoly to set the price. Off-patent drugs face market competition if there are multiple competitors. The problem in the off-patent market occurs when there is only one or two off-patent drug companies making a drug.

#### POLICY OPTIONS TO INCREASE COMPETITION, DECREASE DRUG SPENDING, AND IMPROVE PATIENT ACCESS WHILE ENCOURAGING INNOVATION

We are examining policy options for the HELP committee to consider. We have divided them into two categories:

1. Policies that increase the level of competition.
2. Policies designed to increase access to pharmaceuticals.

## INITIATIVES TO INCREASE THE LEVEL OF COMPETITION

*1. Curb Use of Limited Distribution Networks that Restrict Ability of Generic Companies to Copy Drugs and Submit ANDAs to FDA*

Generic drug companies need access to brand and off-patent drugs in order to demonstrate bioequivalence to the FDA for abbreviated new drug applications (ANDAs). However, some brand and off-patent drug companies are putting their drugs in limited distribution networks, making it virtually impossible for a generic drug company to access the drug. Hearings at the Senate Aging Committee and House Government Oversight Committee have shown how Martin Shkreli and others have used this tactic to stifle competition for old and off-patent drugs. Requiring drug companies to make their drugs easily available to generic firms would accelerate the introduction of generic drugs in the market and could save \$2.8 billion, according to the Congressional Budget Office.

*2. Include Drugs in Bundled Payments and ACOs*

This is a potential game changer. Most drugs are still paid under a fee-for-service model. Payment reform is moving toward value-based purchasing; however, drugs are typically not included in these approaches. Including drugs in reforms like bundled payments and Accountable Care Organizations (ACOs) would allow the physicians and other providers to make allocation decisions that include tradeoffs between a drug and other treatment modalities. Including drugs in bundled payments and ACOs would fundamentally disrupt the drug purchasing process and lead to more transparent pricing and put doctors in charge of deciding which drugs the person receives instead of the PBM or insurer. The doctor would have the financial incentive to make the decision that is in the best interest of the patient. Drugs are already included in the Medicare DRG payment that hospitals receive; this would simply expand the scope to value-based purchasing arrangements.

*3. Eliminate Rebates in PBMs and PDPs*

PBMs earn most of their profit by getting rebates from the drug companies. The rebate is based on the difference between the list price and the transaction price. Increasing the list price therefore results in greater rebates, which totally distorts the pricing system. The higher list price also means greater cost-sharing for patients because cost-sharing is typically based on the list price. Forcing the PBMs and indirectly the prescription drug plans (PDPs) to pass on all of the rebates to the government, health plan or self-insured company would eliminate the market distortions, reduce prices, and should be used to reduce premiums or patient cost-sharing. The PBMs would earn a fee for their services instead of a portion of the rebate. Giving the rebate to the patient—although it sounds good in principle—serves to distort the market since the patient would no longer be affected by the price and the drug company could increase the price even further. Some “skin in the game” for patients is needed to keep prices down, as long as it does not prevent access.

*4. Restrict Pay for Delay Behavior*

Branded drug companies have used a variety of mechanisms to prevent generic drug companies from entering the market, including paying them to delay the introduction of a competitor generic drug. While the courts have continually said this is illegal, some abuses continue. Litigation is time-consuming and allows the branded drug company to continue to earn substantial profits while the case is still being litigated. An alternative is to penalize the generic company that applies to be the first entrant into the market after the patent expires, but then does not actually manufacture the drug. Congress could, for example, give the FDA the authority to keep the generic manufacturer from making an ANDA application for a second drug until it has actual sales on its first application. Generic drug companies would be motivated to get the drug to market as soon as possible and pay for delay would be eliminated.

*5. Restrict Use of Patient Assistance Programs*

While public programs like Medicare and Medicaid do not permit drug coupons, they do permit patient assistance programs that provide billions of dollars in financial support to Medicare and Medicaid beneficiaries. Some of the largest foundations in the United States are now patient assistance programs sponsored by drug companies, with several of them giving out almost a billion dollars a year. The problem with patient assistance programs is that they allow drug companies to raise prices while keeping patients immune from all cost sharing. A recent *Wall Street Journal* analysis suggests for every \$1 million funneled to patient assistance programs by drug companies resulted in \$21 million in increased drug sales. This is problematic considering the IRS considers patient assistance program donations to be charitable

deductions. Again, some “skin in the game” for patients is necessary, as long as it does not harm access.

#### *6. Reduce Abuse of Orphan Drug Designations*

Some branded drugs have multiple orphan drug approvals that extend their period of market exclusivity and give them significant tax advantages. While the Orphan Drug Act had good intentions, the legislation needs revision to prevent companies from applying for multiple orphan drug designations and receiving multiple approvals and therefore market exclusivity extensions for the same drug. Revision of the law would lower prices by moving branded drugs to the generic market sooner.

#### *7. Restrict Mergers of Generic Drug Companies*

The Hatch Waxman Act effectively controls drug prices for generic drugs when there are three or more generic competitors manufacturing the drug. However, the generic industry has undergone a series of mergers that have reduced the number of competitors and lessened price competition. Recently, the largest and the third largest generic manufacturers merged. Because generic drugs are responsible for almost 90 percent of drug sales in the United States, Congress and the FTC need to take a careful look at the level of competition in the generic market to make sure there are more than three competitors for all generic drugs. The recent mergers have lessened the level of competition in the generic market.

### ADDITIONAL INITIATIVES TO IMPROVE ACCESS TO PHARMACEUTICALS

#### *1. Revise Medicare Catastrophic Drug Spending Rules*

The main reason for the rapid increase in Medicare Part D spending is the advent of the high-priced specialty drugs costing more than \$7,000, for which the Medicare program pays 80 percent of the cost. In spite of paying 80 percent of the cost, Medicare is prohibited from negotiating these drug prices. MedPAC has proposed shifting 80 percent of the cost to the PDPs and dropping the Medicare proportion to 20 percent so that the PDPs have a greater incentive to negotiate lower drug prices for these specialty drugs. However, this could cause the PDPs to discriminate against people with multiple chronic conditions (who take lots of drugs). Instead, Medicare should be able to negotiate prices directly for these high-priced specialty drugs. If negotiation fails, Medicare could use reference pricing, binding arbitration or value-based pricing to set prices.

#### *2. Enact Price Gouging Legislation*

This year, the State of Maryland enacted bipartisan legislation to empower the Attorney General to take legal actions against drug companies enacting “unconscionable” price increases for off-patent drugs with fewer than three competitors. It is designed to keep people like Martin Shkreli from raising prices on an off-patent drug for which there is the only one manufacturer. It is the first legislation to address the problem of rapid price increases for off-patent drugs. Congress could consider similar legislation to stop actions by people like Martin Shkreli.

#### *3. Allow One Single Federal Agency To Negotiate Drug Prices*

Currently many different government agencies negotiate drug prices, with each Federal agency paying very different rates with different or no formularies. Looking at those 30 drugs for which we can directly compare prices, the Medicare program pays 30 percent higher prices than the DoD. Considering the similarities in the drugs needed by these agencies, the Federal Government would have a better procurement process if there was only one Federal agency purchasing drugs. Because the prices are highest in the Medicare program and Medicare beneficiaries pay the highest cost-sharing, Medicare beneficiaries are the biggest losers when government agencies pay different prices. While some Federal agencies might pay more in one price arrangement, the entire Federal Government could pay less. Savings would be dependent on where the single Federal entity set the price—at the highest level (Medicare), the lowest (DoD), or at the weighted average.

#### *4. Use 1498 Authority To Negotiate Drug Prices*

The Federal Government has the existing authority (28 U.S.C. §1498) to take away the patent of a company, such as a pharmaceutical company; provide reasonable compensation to the drug company for the use of the patent, and allow a generic manufacturer to manufacture the drug. The Department of Defense, the National Gallery of Art and many other Federal agencies have used this authority to purchase patented materials at reasonable prices. Health and Human Services Secretary Tommy Thompson threatened to use 1498 authority to purchase Cipro following 9/11 and Bayer lowered its price in response. The State of Louisiana is cur-

rently considering asking Secretary Price to use his authority under 1498 so that Louisiana can purchase hepatitis C drugs for the uninsured and Medicaid populations.

The CHAIRMAN. Thank you, Dr. Anderson.

Thanks to all of you; very interesting testimony.

We will now begin a round of 5-minute questions. At about 11:20, I am going to ask Senator Cassidy to come over and chair the committee so that I can attend another hearing for a few minutes.

One purpose of this hearing is to see if we can establish some base facts. Let me ask this question and if you can answer it as close to yes or no as possible, I would appreciate it.

I have heard drug spending accounts for roughly 15 percent of health spending. Of that 15 percent, 10 to 11 percent is on drugs purchased at the pharmacy or ordered online, and 4 or 5 percent is spent on drugs given in the hospital and the doctor's office.

Is that correct? Does anyone disagree with that?

[Panel nods in assent.]

Thank you.

Dr. Howard, you said, I believe, that 30 percent of branded generic prescriptions had a zero out-of-pocket cost for the patient in 2016. In other words, that when the patient picked up the prescription at the drugstore, 30 percent of the prescriptions cost zero. Dr. Adam Fein has said that as well in a meeting that we had here.

Is that an accurate reflection of what you said?

Mr. HOWARD. Yes, it is.

The CHAIRMAN. Does anyone disagree with that of the panel?

[No audible response.]

Thirty percent of the prescriptions, brand and generic, picked up at the pharmacy or online costs the patient zero.

Mr. Mendelson, you observed, if I heard your testimony correctly, that patients are bearing more of the cost of prescription drugs out-of-pocket in an effort to keep monthly premiums low.

Is it accurate to say, and I would ask this of other panel members as well, that in some situations or many situations consumers are paying more for drugs while insurance companies and employers are paying less for drugs.

Did I say that right or how would you characterize it?

Mr. MENDELSON. I would characterize it as saying that changes in benefit design are resulting in consumers paying more.

The CHAIRMAN. Changes in benefit design. Now, what does that mean to the untutored of us?

Mr. MENDELSON. As the cost sharing associated with a drug goes up, you are paying more of the portion of that price.

The CHAIRMAN. Then who is paying less if the patient is paying more?

Mr. MENDELSON. It depends on whether the cost—I know you do not like the word “depends,” no Senator ever does—but it depends on whether the cost is going up as a result of a rise in the price of the drug or just the change in the benefit design.

What is happening is that patients are being asked to pay a larger and larger percentage of the cost of the drugs that they take.

The CHAIRMAN. That would mean someone is paying less. Is that right?

Mr. MENDELSON. That is right. It could be reducing the premium.

The CHAIRMAN. It would be the employer or the insurance company. Right?

Mr. MENDELSON. Or it could be reducing the premiums to the consumer.

That is the other thing that is important, which is that if a health plan can reduce premiums to the consumer, they want to do that, and part of the way they are doing that is by putting higher prices for drugs to consumers at the same time.

The CHAIRMAN. To lower the price of the premium.

Any other comment on that? Dr. Anderson.

Mr. ANDERSON. Essentially what we are seeing in the private insurance market and the PBM's, is about a 3 percent growth rate in drug expenditures. What we have is if the price—

The CHAIRMAN. A 3-percent growth rate.

Mr. ANDERSON. The expenditures by the health insurers, by the employers, by people. It is not that the prices are going down for the employer; they are just not going up as fast.

What we have is a balloon here. What happens when the price increases are people, the insurance companies, squeeze the balloon a little bit to keep their price increase by only going up by 3 percent. Somebody else has to pay part of that increase and that is the consumer.

When the employers squeeze the balloon, the consumer pays.

The CHAIRMAN. Who else had a comment? Dr. Howard.

Mr. HOWARD. Yes, I am sorry. I just wanted to comment.

What happens when the person goes to the pharmacy to pick up their prescription, the pharmacy does not know the rebate. They are reimbursed based on what is called, I think, the average wholesale cost.

The coinsurance that a patient is paying is based on the price that the pharmacy has. That rebate is given to the PBM. I think Dan commented that that rebate is then, at least some portion of it, passed along to the employer. The patient is experiencing a coinsurance based on a list price and that is a problem. That is what we are honing in on now.

As Express Scripts said last year, it held cost growth for its commercial clients to under 3 percent, but more of that cost is being shifted to patients buying these specialty medicines.

The CHAIRMAN. I am afraid I am out of time, but I am going to submit to each of you two or three questions, if I may in writing. One of them is going to be if we should not focus on the list price, then what should we focus on instead in trying to understand pricing?

Senator Murray.

Senator MURRAY. Thank you very much, Mr. Chairman.

Before I ask the witnesses any questions, I wanted, since you are going to be leaving, to ask you a question. I really do appreciate you having this hearing, prescription drug prices is extremely important. I appreciate this and it is an important topic. I will have questions.

You have not yet scheduled a hearing on the Republican Trumpcare bill. I know you are a part of the discussion. You know

what is in it. We have no idea. We have not seen it. The people we represent do not have any idea. Senator McCaskill raised this at a hearing, powerfully, last week and I want to raise it here too.

Do you intend to have any hearings before the bill comes to the floor?

The CHAIRMAN. I have none planned, Senator Murray, but let me respond to that in two ways.

No. 1 is that bill, if you are referring to the House bill, would be referred to the Finance Committee, not this committee. So you might take it up with Chairman Hatch.

No. 2, I had a hearing in late January, early February. We had terrific witnesses. My hope was to focus on the individual market and changes that we might agree on in a bipartisan way. Most Senators came to the meeting and made their Obamacare speeches that they have been making for the last 7 years.

I would summarize it by saying that the witnesses did very well at the hearing. The Senators did very poorly.

If we are not able to focus in a bipartisan way when we have a bipartisan hearing, I do not think there is much promise for a bipartisan result.

Which leads me to my third point, which is that this is a hearing that you asked for—

Senator MURRAY. Right.

The CHAIRMAN [continuing]. That other Democrats asked for, and that Senator Cassidy and Republicans asked for. We agreed on who the witnesses should be. We have exceptional witnesses today. It is a chance to address drug pricing, which is important to every American family.

I would think that this committee is a group of grown-up adults who are able to do more than one thing at a time.

We could discuss Obamacare, if you would like, but today we are trying to discuss drug pricing which is up to 15 percent. You brought up the issue.

Senator MURRAY. I just asked you a question.

The CHAIRMAN. You asked me the question about Obamacare, which is not the subject of today's hearing.

Senator MURRAY. I agree.

The CHAIRMAN. If that is the way you want to spend your time, fine. I do not know why I should call hearings requested by the Democrats with bipartisan hearings when you will not focus on the hearing.

Senator MURRAY. Mr. Chairman, I appreciate that you are having this hearing. I also would very much appreciate that we have a hearing on a bill that we are going to see that our folks have not seen, people across the country have not seen.

When we passed the ACA, we had 57 bipartisan HELP committee hearings, and meetings, and roundtables. I will just say that that is disconcerting.

The CHAIRMAN. You passed the ACA in the middle of a snowstorm with 60 votes and crammed it down the throats of Republicans.

Senator MURRAY. Well.

The CHAIRMAN. If you want to talk about that, we can. Today we are talking about drug pricing.

Senator MURRAY. We are talking about drug pricing. It is an important part of the healthcare program, but I think people in the country are deeply worried about what is happening to the healthcare system.

Mr. Coukell, let me go to you first.

Our hearing today is about the supply chain impacts and costs, and we have heard that the interactions between drug companies, pharmacies, and payers is a complicated one, but let me ask you a simple question.

We all know prescription drug prices are harder and harder for our families to bear. Some Republicans have been blaming this on the skimpier insurance coverage that forces patients to pay more out-of-pocket.

If that were the case, the total spending on drugs should stay constant as just the patient share of the costs would be increasing.

Based on your testimony, my understanding is that total spending on drugs is not only increasing, it is increasing faster than spending on other types of healthcare services.

Is that correct?

Mr. COUKELL. That is correct, Senator, and it is projected to continue increasing at about the current rate through 2021.

Senator MURRAY. Why is that?

Mr. COUKELL. That is based on a combination of high launch prices of new drugs, and year-on-year increases in the prices of brand drugs that are on the market. Drug spending is also being increased, by the increased volume growth as the population ages and we use more drugs. Those are the three major drivers of drug spending.

Senator MURRAY. Dr. Anderson, about 10 to 15 percent of U.S. healthcare spending goes to pay for prescription drugs. We established that. That is a cost patients feel every day.

I wanted to ask you in my short amount of time left, how can we tell if a high-priced new drug—you mentioned some of the bipartisan report were produced—how can we tell if a high-priced new drug is actually saving money down the road?

Mr. ANDERSON. We really cannot in most cases. We have some methodologies out there that are trying to do that, but it is exceedingly complicated.

That is why I would rather have the doctor make the decision as to which drug you get by giving that doctor the financial incentives to make the choice given the fact that they have a certain amount of money to spend.

Senator MURRAY. Thank you very much.

The CHAIRMAN. Thank you, Senator Murray.

Senator Cassidy.

#### STATEMENT OF SENATOR CASSIDY, M.D.

Senator CASSIDY. Thank you all.

A couple of things. Let me just make a comment at the beginning. I am a little bit betwixt and between the two sides.

I will say as a physician, when I was a medical student, one of the most common surgeries was gastric resection, taking out a part of the stomach for peptic ulcer disease. Along comes Cimetidine,

which is now an over the counter drug, and we just stopped doing the surgery.

Then when I was a resident and fellow, Crohn's disease surgery was so common. No one does Crohn's disease surgery any more because now we have these new drugs that just eliminate it.

Yet, on the other hand, I will agree. Dr. Anderson, you made the point and it was made by others, that there are some drugs that are so priced that some people do not achieve the benefit.

I always said we have a social contract with pharmaceutical companies in which we reward them for the risk and the social benefit they bring. I was on a call the other day and somebody said, "Well, our first loyalty is to our stockholder, our shareholder. We should charge whatever we can."

It seems like our social contract has now fallen apart. I just say that as a physician that understands there are lifesaving medicines which some people cannot access.

Dr. Anderson, you mentioned the Louisiana Hepatitis C. I am actually working on that. I am a hepatologist. I did a spreadsheet and saw that we could actually save money on long-term care—cirrhosis, a better share of the cancer, et cetera—if we upfront the treatment. The question is how do you pay for it? I do think that is something that we have to address.

Let me toss out something which is kind of radical.

When I look at the rebates, I am not sure that on net the rebates are actually bringing benefit to our society. As a physician, I look at the person paying cash and she is not benefiting from that rebate unless that is one of the rare companies, like CVS, I think you mentioned Dr. Howard, that does a point of sale rebate.

One of you mentioned in your testimony that we are pushing people more rapidly into the catastrophic portion of their Medicare Part D by a higher price. Sure, it is rebated, but the person is paying out-of-pocket. So their true out-of-pocket cost is inflated. They are moving more rapidly into the Medicare Part D.

Both for that cash person and their deductible, or with their health savings account, and the Federal taxpayer who is pushed more rapidly into the catastrophic portion. It seems like the rebate is kind of not working as well.

Mr. Mendelson.

Mr. MENDELSON. Yes. I would respectfully challenge that. I think that rebates are benefiting American consumers. They are benefiting American consumers because they leverage effective price competition and they ultimately reduce—

Senator CASSIDY. Let me interrupt. Why not just have a price based? When my wife buys jeans, she does not get a rebate from Levi's or Lee. She actually just gets a net price.

Tell me why that does not just translate into a net price?

Mr. MENDELSON. Rebates are a way that pharmaceutical companies give price concessions.

Senator CASSIDY. I accept that. I guess what I am just stumbling on, why not have a little upfront price which would be the ultimate concession?

Mr. MENDELSON. Because when drugs are first launched, there is a launch price and then competition comes in. The Hepatitis C market is a great example of this.

Senator CASSIDY. Somehow I think we are talking past each other.

Mr. COUKELL. Senator, may I?

Senator CASSIDY. Yes.

Mr. COUKELL. If your wife were buying tens of thousands of pairs of jeans, she would go to the manufacturer of the jeans and say, "I do not want to pay list price. I am going to buy a lot of jeans and let us have a negotiation about what I should pay."

Senator CASSIDY. I get that, but when you look—

Mr. COUKELL. If we do not have that mechanism, then the question is how do we set a price for drugs? Some other countries, the Government sets that price.

Senator CASSIDY. Mr. Coukell, let me just say, though you can either do that with a rebate or you can say, "Give me a better price upfront." If I am buying a fleet of automobiles from Ford, I say, "Just knock \$1,000 off," or I could say, "Give me \$1,000 later."

The reason I say that is because that manufacturer's price is factoring in to what the person paying cash is paying and therefore that inflates their true out-of-pocket costs, moving them more rapidly into the Medicare Part D.

Mr. Howard.

Mr. HOWARD. Senator Cassidy, I think you make a very interesting point, which is companies could shift to a flat discount, as per CVS has done, make it available at the point of purchase.

They could also turn to providers and say—the reason they give the discount is to get on the formulary—but they could go to providers under some systems and say,

"Here is your mix of patients. These are the medicines they need. Here is the price we will charge you and because you are operating in a value-based contract or a capitation contract as an HMO, you can save money. We will demonstrate and share our savings with you."

There is a different way of thinking about this that utilizes health technologies and informatics we have at our disposal and that are coming online to try and make the value proposition clearer to the provider and the patient.

Senator CASSIDY. I get that. It seems like there is a complexity there which is so incredible, that it is hard for one side of that to actually fully understand if they are getting the value that they are promised.

Mr. ANDERSON. It is absolutely true that it is totally confidential. What you have got to recognize is the consumers, if you go to the pharmacy with your insurance card, you might be paying more because you have insurance than if you did not have that insurance card. That is because of the rebates and those activities.

Senator CASSIDY. I will say that Louisiana is one of the few States that has said that pharmacists cannot be gagged. Meaning that they can inform a patient that she would pay less if she paid cash as opposed to paying her deductible, and that may be something we wish to look at.

The CHAIRMAN. OK.

Senator CASSIDY. Which is a very pro-consumer, pro-patient perspective.

The CHAIRMAN. Thank you, Senator Cassidy.

It is hard within 5 minutes to really dwell into this for each Senator. We might explore, as time goes on, whether we want to have a different forum, a roundtable, for example, where we can have more of a conversation and discussion between, perhaps, the four of you and Senators who are especially interested in this issue.

I am open to any kind of discussion that will help us understand what we are talking about. We talk about list prices, rebates, et cetera.

Senator Casey.

#### STATEMENT OF SENATOR CASEY

Senator CASEY. Mr. Chairman, thank you.

I want to thank you and Ranking Member Murray for having this hearing, and for those that made it possible. It is a critically important issue and I know we are going to have more than one.

I have to say, that stands in contrast to what is not happening on an even larger issue. This is a big issue, drug prices and affordability.

The even larger issue of what is going to happen to our healthcare system because of what the Senate Republican members are doing right now. I would hope that we would have hearings on the healthcare proposal just like we are having hearings on this issue.

In my judgment, there are lots of ways to argue against what happened in the House and what likely will happen in the Senate because there is reporting, just last week, that the Senate bill will be 80 percent of the House bill. So it is substantially similar.

In that case, just in terms of the Medicaid proposals, which I do not think will change all that much House to Senate, it is not repeal and replace. In my judgment it is repeal and decimate when it comes to children who get their good healthcare through Medicaid. People with disabilities in my State over 720,000 people have a disability and receive Medicaid, and about a quarter of a million seniors cannot get into a nursing home absent Medicaid.

If we enact what is being proposed in the House bill, if we enact what is being, credibly assessed as to where the Senate bill is, a lot of those Pennsylvanians will be hurt. I hope we have a hearing on that bill as well.

This issue for people in my State is of paramount concern. Other than questions about national security on the domestic side of what people are concerned about, and I would say other than maybe healthcare itself more broadly, I am asked about no issue more than drug prices.

It is of great concern to people. It is making it very difficult for people to get the medications they need. Millions of Americans do not get the medication they need because of prices.

Dr. Anderson, I will start with you. You heard what I said about Medicaid and what would happen in the event that a bill is enacted substantially similar to what has been talked about and what has been legislated.

Can you discuss high drug prices, especially around curative treatments like Sovaldi, which can cure someone with Hepatitis C, but will impact State Medicaid programs under capped funding?

Mr. ANDERSON. I would be glad to.

If you have a drug like Hepatitis C, and people have it at the age of 40 or 50, it makes it difficult for them to work. Some of them are in prisons, many have been on Medicaid.

However the benefit, in terms of financial benefit, of them getting ill typically does not accrue to the Medicaid program. They get ill when they are eligible for Medicare, and so the State is putting out all of this money, and the Medicare program is the one that is benefiting.

Figuring out a way for the State to have an incentive to invest in a curative disease, an infectious curative disease is absolutely important.

Senator CASEY. One of my basic concerns is that one of the changes that will take place at the State level is to a large extent, maybe not completely, but to a large extent if the Medicaid changes that are being proposed were enacted, the Federal officials would wash their hands of it. State officials, who have to balance their budgets, would have to take up and deal with the consequences, I should say, of no more guaranteed funding for Medicaid.

Mr. ANDERSON. That is exactly why we are working with Senator Cassidy in Louisiana to try to do that. We would be happy to work with Pennsylvania or any State as well.

Senator CASEY. I am grateful.

In the remaining time I have, Mr. Mendelson, on Page 5 of your written testimony, you cite the higher out-of-pocket costs as a key factor in patients' adherence to prescribed medications. For Americans with chronic diseases, adherence to a prescribed medication regimen can reduce unnecessary health spending such as hospital stays, doctor visits, et cetera.

Can you talk about that part of your testimony?

Mr. MENDELSON. Absolutely. Adherence is a key aspect and especially when a patient is using a medication that is of critical benefit to them or, frankly, reducing health system costs like the cardiovascular generics that we discussed before.

There is tremendous potential in fielding digital compliance programs where patients are tracked and the plan, or the Pharmacy Benefit Management company, is able to remind the patient, make sure that they are adhering to the therapy. Those are programs that could very well be supported by this committee.

Senator CASEY. My final point and I know I am done. I do not know how you—even if the result of these hearings over time ended with lower drug prices—I do not know how that is benefiting many people when you rip away healthcare to 23 million people, which is the CBO number based upon the House bill. If you do the math on the Senate bill—

The CHAIRMAN. Time is up, Senator Casey.

Senator CASEY [continuing]. You have millions of people without Medicaid coverage.

The CHAIRMAN. Senator Young.

#### STATEMENT OF SENATOR YOUNG

Senator YOUNG. I thank all of our panelists for being here today. Each of you indicated in your written testimony that you alluded to the piloting of innovative outcomes-based contracts by insurers

and by biopharma companies. I would like to explore this idea of outcomes-based contracts with each of you.

Can you first explain how these contracts work and perhaps what their potential might be to lower drug costs for patients? Any of you can respond.

Mr. COUKELL. There is a vast range of potential ways these contracts could work.

Some could be purely financial instruments around a volume of sales and so on. Some could tie reimbursement payment for the drug to achieving specific outcomes, preventing hospitalization, or lowering cholesterol to a certain level. There are a lot of ways they can be structured.

This is still very new territory. There are not that many of these arrangements in place. Avalere just did an analysis that Mr. Mendelson could talk about.

There is relatively little in the public domain about how they are structured. They are complex to negotiate. They require a lot of data to monitor and followup on, and it is as yet unclear whether they will reduce spending.

Senator YOUNG. Yes.

Mr. MENDELSON. Yes, I am sorry, if I could?

Our analysis actually showed that 70 percent of health plans were very enthusiastic about initiating these contracts, and that 40 percent had actually initiated these contracts and felt they were successful.

I completely agree with Allan's characterization of the programs, but these are critical programs that are in place today, and I think really could be facilitated by making a few small changes to enable better contracts between health plans and pharmaceutical companies.

Senator YOUNG. To followup on that, are there policy barriers to implementation of these contracts?

Mr. MENDELSON. Yes.

Senator YOUNG. If so, what are they?

Mr. MENDELSON. I would point to three.

The first is that certain aspects of the Stark Regulations prevent the engagement with patients to make sure that some of the compliance programs—for example, that Senator Casey mentioned—could actually be adopted.

The second, ironically, is Medicaid best price where sometimes a pharmaceutical company does not want to enter into an agreement with a health plan if they think that the price that they will ultimately grant will go below what they granted to Medicaid.

It is ironic in the sense that it is really preventing the healthcare system from moving forward on the basis of the price floor that was set under Medicaid. So those are two.

Then I think there is a third set of policies around enabling more digital engagement by plans into the pharmaceutical area, and I would be happy to followup with more detail on that for the record.

Senator YOUNG. I will look forward to that.

Can others identify policy barriers to implementation of these contracts? Or, if you have strong opinions about their viability and effectiveness as we transition from a fee-for-service model, I would like to hear your thoughts as well. Yes, Doctor.

Mr. HOWARD. Dan is absolutely right.

I just had one thing. From the perspective of the FDA—and the engagement of companies, providers, and payers—there can be limitations on what companies can provide in terms of what is called off-label information on a product's effectiveness or safety profile that is not contained on the label. It is gathered through other sources, other clinical sources, electronic medical records, other studies.

Being able to transmit that information and incorporate it into these contract designs, testing new value and pricing arrangements, would be very helpful. The FDA's concern is that manufacturers would not have an incentive to go back and get new label indications, or expanded label indications.

The FDA could create safe harbors for these and then develop the use cases where they could capture that information and more rapidly expand the label and update the label more quickly than they do today. That would also allow for drug repurposing, drugs competing head to head based on their real world performance, which is another way to drive competition.

Mr. ANDERSON. What I would be concerned about in this formula approach is determining the value of a human life.

You really need to do that in most of these formulas and I do not know how you are going to do that. If you want to try to do that, go ahead. Also, every single patient—

Senator YOUNG. Would we, perhaps, look to some other areas, through regulation? We have seen that regulators here at the Federal level on a daily basis do determine cost value. Whether it is through auto safety rules, or other decisions over at the FDA, they do, in fact, determine a cost value, as uncomfortable as that notion is to all of us, a cost value—

Mr. ANDERSON. Right.

Senator YOUNG [continuing]. Per life.

Mr. ANDERSON. So the first thing you would have to do is that.

Senator YOUNG. Yes.

Mr. ANDERSON. The second thing is each patient is unique. Talking about a value for a drug for you is different than for Senator Collins.

Senator YOUNG. Dr. Howard and Mr. Mendelson, this cost value, they see that as a red herring based on their facial expressions.

Mr. ANDERSON. Right.

Senator YOUNG. I want to get that on the record.

The CHAIRMAN. Thank you, Senator Young.

Senator Franken.

#### STATEMENT OF SENATOR FRANKEN

Senator FRANKEN. Thank you, Chairman Alexander and Ranking Member Murray for holding today's hearing on prescription drug costs.

I also want to thank Senator Cassidy and the eight other Members from both sides of the aisle who joined me in requesting this hearing. I hope that we can continue this work together to tackle prescription drug costs and that is why we are here.

I am also glad that we will have additional hearings on prescription drugs. The roundtable is a great idea, Mr. Chairman.

I do agree with the Ranking Member and with Senator Casey that we do need to have hearings on the current effort in the Senate to repeal the ACA. I think the fact that we are not, should show the people of Tennessee, once again, that the Chairman is a rabid right-wing partisan.

Is that helpful for you?

[Laughter].

The CHAIRMAN. Actually, that might get me through the next election.

Senator FRANKEN. OK.

The CHAIRMAN. Thank you for that.

[Laughter].

Senator FRANKEN. Our No. 1 focus today and always needs to be on patients.

Consider Carol from St. Paul, who has M.S. and has been denied coverage for her drugs that charge nearly \$3,000 for her co-payments.

Or take Clare, who lives in Stillwater, MN. Clare used to pay \$60 for her Remicade treatment for her rheumatoid arthritis. My mother had rheumatoid arthritis. But the price shot up to \$1,400 for her prescription. Clare had to choose. Take her medicine or keep her home. It has been 2 years since her last treatment, and now she is having trouble holding a knife and fork.

No one should have to choose between affording their medications or their home.

Clare is angry. Her condition now interferes with her ability to do basic tasks and she feels like she is being robbed of her ability to age gracefully.

Frankly, I am angry too. It is our job, all of us here, to help people like Clare.

These stories are not unique to Minnesota. I have given all of you these stories from your constituents and your States. I hope that you will read them, everyone here, and internalize them, and make these stories your test of whether what we are doing here is good enough.

Senator Cassidy has been talking about the “Jimmy Kimmel Test,” and I am glad he has been. For drug prices, let us use the “Clare Test.” Will the proposals we support help Clare keep her home and get the medicine she needs to hold her knife and fork.

That is why I worked with 15 of my colleagues, many of them here today, to introduce comprehensive legislation to bring down prescription drug prices. This bill includes more than a dozen policies to increase transparency, improve affordability, reward high value innovation—I thank the Senator from Louisiana for bringing that up—and accelerate competition.

I do not expect every member on this committee to endorse all the provisions in my bill, but I hope we can work across party lines to build on them.

I would like to turn to my questions.

Skyrocketing drug prices obviously affect Clare, but they actually affect all of us.

Mr. Coukell, can you describe for Americans who are listening today who do not take expensive prescription drugs all the different ways that high drug prices affect them as well?

Mr. COUKELL. Thank you, Senator.

We all pay the cost of prescription drugs. We pay it through insurance premiums that we pay. We pay it indirectly through insurance premiums that businesses pay. We pay it through taxpayer programs that support Medicare, and Medicaid, and the V.A., and DoD, and all of those programs.

Every prescription that is covered by insurance ultimately is covered by the American public.

Senator FRANKEN. All of you would agree, right?

[Panel nods in assent.]

I only have 30 seconds left, Mr. Acting Chairman, can I go to my next question?

SENATOR CASSIDY [presiding]. Yes.

Senator FRANKEN. Thank you.

Reuters recently conducted an investigation on price increases for the top 10 drugs sold in the United States. Between 2011 and 2014, all of these 10 drugs had price increases of at least 50 percent.

Clare's arthritis drug, Remicade, went up 63 percent. Humira, another arthritis drug, had 126 percent price increase. M.S. drugs, too, have increased from about \$8,000 a year to upwards of \$60,000 a year annually, even though many have been in the market for years.

Mr. Coukell, or anyone who wants to answer this. How do drug companies justify these year over year price increases? For example, are their products improving in any way from year to year to justify the price? Or, are companies conducting valuable new research and development on these existing drugs? If neither of these, what do you think drives these increases? Again, for anyone, but I will go first to Mr. Coukell.

Mr. COUKELL. Thank you, Senator.

It is always important in this space to recognize when we are talking about list prices or net prices. Both are important.

Net prices are projected to rise 2 to 5 percent a year over the next 5 years. So compounded, that is 10 to 30 percent.

List prices are rising much faster and rebates are rising with them. For the patient who is paying an out-of-pocket share based on a list price, or something like a list price, that has huge implications at the pharmacy.

Obviously, once the products are on the market, there are some ongoing costs for the companies, but if the drug comes to market at a price that reflects its value, it is unclear why it would increase faster than medical CPI.

Senator FRANKEN. I am sorry. I will be here for a second round. Thank you for your indulgence.

SENATOR CASSIDY. Senator Collins.

#### STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you.

Dr. Anderson, let me start by saying it is great to see you here again. You were extremely helpful last year when the Senate Aging Committee conducted a year-long investigation into the four drug companies that had acquired decades-old, off-patent drugs, and

then dramatically increased the prices, in one case by literally 5,000 percent overnight.

What we found in that investigation is that companies were able to ward off competition by putting their drugs in closed distribution systems, or specialty pharmacies that made it very difficult for generic companies to get sufficient quantities of the drugs to do the bio-equivalency studies that are required by the FDA.

We particularly found that there were problems with abuses of the Risk Evaluation and Mitigation Strategies program. That is what is known as REMS. It is used for drugs with increased risk factors. Instead, it was being misused to prevent potential competitors from getting the drugs that they needed for the bio-equivalency studies. Indeed, Janet Woodcock, from the FDA, testified that this was a real problem.

Could you elaborate on that issue and what we could do to ensure that companies do not block access to the quantities of drugs that are needed for the bio-equivalency studies?

Second, since this is going to be the only question I am going to get, another idea would be to amend the Medicare Part D contracts that outline the participation in the formularies that are covered by Medicare Part D to require companies participating in Part D to make available sufficient quantities of their medications for these bio-equivalency exams conducted by potential competitors.

Could you comment on those two issues?

Mr. ANDERSON. I will do my best.

Senator COLLINS. Thank you.

Mr. ANDERSON. Thank you for those kind words.

It has been great to work with you and your staff over the last year and a half helping to put together your report, and then the legislation I know that you have been able to get through this committee. It has been a great effort, and I appreciate my little part in that activity.

What is happening right now is you have this REMS program which is established by the Congress and it is to make sure that the drugs are safe.

However, what is happening is that companies are using this idea to block other companies from actually getting access to the drug. People like Martin Shkreli, which your report showed, essentially created this entity called a limited distribution chain to keep everyone from getting access to his drug who was a competitor to him, so no one could actually get access to the drug.

There are a number of ways that you and others could deal with this problem. One of which is to essentially say to every drug company, "You have to make that drug available to anybody who wants to manufacture it."

I was on a panel with Janet Woodcock over in Government Oversight a little while ago, and she said,

"I cannot do anything about it. I can say that you can make it available if it is on REMS, but I cannot force you to make it available."

I think only the Congress can essentially say that.

There is about a \$3 billion savings that the Congressional Budget Office has estimated could happen if essentially Congress were simply to say to the company, "You have to make that available."

There are a number of bills, and you have one of them, that are about that particular area.

You could amend the Part D activities. You could do a whole variety of different activities, but essentially the idea here is to make sure that there is, in fact, competition in the marketplace.

Senator COLLINS. Thank you so much. Those are clearly areas that we need to pursue.

Thank you, Mr. Chairman.

Senator CASSIDY. Senator Bennet.

#### STATEMENT OF SENATOR BENNET

Senator BENNET. Thank you, Mr. Chairman.

I would like to thank the Chairman and the Ranking Member for holding this hearing on drug pricing.

It is a critical issue for people all across Colorado. I hear about it regularly and I have heard about it over the last several weeks as I have held town halls all over my State in republican and democratic parts of Colorado where people are expressing their deep concern—I should say to my colleagues on the other side of the aisle—over the House-passed healthcare bill.

Based on what we know, 23 million people may stand to lose health insurance, and those who are older and sicker may be charged more. The effect of this is going to be felt more in rural areas than in urban areas.

In Otero County, where I held one of these town halls, the republican part of my State, 43 percent of the people who live there depend on Medicaid. I think they have a right to know what is in the bill, what is in the Senate plan. A right to know what is being currently drafted behind closed doors. Their health, the well-being of their families is at stake.

In 2009, while amending the process the Democrats used to pass the Affordable Care Act, Speaker Ryan said, “I do not think we should pass bills that we have not read, that we do not know what they cost.”

He said,

“Congress is moving fast to rush through a healthcare overhaul that lacks a key ingredient, the full participation of you, the American people.”

Speaker Ryan said,

“Congress and the White House have focused their public efforts on platitudes and press conferences, while the substance and the details have remained behind closed doors.”

In 2010, Leader McConnell said,

“When it comes to solving problems, Americans want us to listen first and then if necessary, offer targeted step-by-step solutions. Above all, they are tired of a process that shuts them out. They are tired of giant bills negotiated in secret then jammed through on a party line vote in the middle of the night.

“It should be clear now, Americans are tired of grand schemes imposed from above.”

They said this about a process that took years, literally years, and provided numerous opportunities to members of both parties to provide input. Almost countless bipartisan hearings were held, countless bipartisan roundtables were held. Hundreds of amendments were considered. Republican amendments were adopted in the process.

When the bill came to the floor, the Senate spent 25 days in broad daylight in front of the American people debating the health reform bill. We have not had a single hearing about this product, which may be on the floor and voted on next week. Not a single hearing. What an abusive process. At the very least, we should meet the standards that Speaker Ryan and Leader McConnell set for the Affordable Care Act.

I say to my colleagues on both sides of the aisle based on the hearings that I held, the town hall meetings that I have held in Colorado. There is going to be a lot of grief that is going to come to this body if we do not slow down and have the kind of public discourse we should be having about 16 percent of our economy and something that affects so materially every single family in our States.

I am glad we are having a hearing today on drug pricing because it is one of the things I hear about at every single one of my town hall meetings. As I mentioned, I think people do not understand why people in America seem to pay such a higher price than people around the world do.

I wanted to ask with my remaining time a question of the panel. It seems to me, based on your testimony and other work that I have seen, that we really need different solutions to address different categories of the drugs.

I would like to ask first whether you think my categories are off-base or on-base. Second, what would you say are the ways we could most materially affect the price of drugs.

The categories, I would suggest, are specialty drugs which are innovative treatments and cures that do not have a competitor, branded drugs that may not have a generic version, but may face competition with drugs that treat the same disease, and generic drugs.

I would ask the panel, do you agree? I have 2 minutes left, so I am just going to go down the row starting with Mr. Mendelson.

Do you agree with this break down and the need for different solutions to address the rising costs of each of these categories? What policy would make the biggest difference, Mr. Mendelson?

Mr. MENDELSON. I agree that different approaches are necessary for products that have limited competition versus those that have robust competition.

My view is that the best opportunity is really in fashioning policies that enhance the competition across all of these different categories, but it has to be selectively done in ways that make sense.

I do want to kind of point out one thing from the prior aspect which is that, as Allan mentioned, drug prices are going up between 2 and 5 percent in the past period. Overall, healthcare prices are going up by about 6 percent.

If these different categories are associated with different levels of price increase and, in fact, for drugs with generic competition, you see substantial reductions in cost.

I just wanted to kind of address that in the premise of the question.

Mr. HOWARD. Just the recognition, to followup on Dan's point, this is a problem we are going to have about every 10 or 11 years because that is when patents expire.

For the first part of this century through about 2012, in 2012 real drug spending actually fell because about a trillion dollars worth of branded medicines went generic.

Then we just need to focus on keeping the drugs in the picture of this is 15 percent of the cost. There is 85 percent of the rest of the costs that is a more appropriate use of medicines and a more appropriate reimbursement for outcomes that includes all of the other pieces of the system can help us to bend the curve.

I would just caution that. Keep them in sight of all the other things they do in the system and the ability to promote competition among other providers.

Mr. ANDERSON. I would just amend your three categories and make it four.

Within the generic space, for most generic drugs where there are three or more competitors, the system works incredibly well. When there are one or two competitors, the system is broken and that is when you get the Martin Shkreli's of the world and that is what Senator Collins and I were talking about.

I would just make that slight modification to your groupings.

Mr. COUKELL. May I quickly?

Senator CASSIDY. Very quickly.

Mr. COUKELL. I agree with that taxonomy. I just want to followup on one point that Dr. Howard made which is this is a 10-year cycle.

The concern here is your first category, which are specialty drugs. We know now that 1 percent of prescriptions are 30 percent of spending. If biomedical innovation continues the way it is going, and let us hope that it does, more and more diseases will fall into that 1 percent and that is the trend that looks unsustainable.

Senator BENNET. Thank you.

Senator CASSIDY. Senator Murkowski.

#### STATEMENT OF SENATOR MURKOWSKI

Senator MURKOWSKI. Thank you, Mr. Chairman.

Thank you to the panel.

Many of my constituents back in Alaska live in communities where there is not a pharmacy in town, or if there is a pharmacy, it is a very small pharmacy and they likely do not stock a lot of specialty drugs. Much of what Alaskans receive by way of pharmaceuticals comes to them through the mail.

A pretty basic question here, then, is if it is going to come through the mail, why not work to expand that available market? For many, they look at our closest neighbor, which is Canada and say, "Well, why can we not just get our pharmaceuticals through the mail and through licensed providers in Canada?"

Obviously, that has been a subject of discussion here in this committee room.

What is the answer to a situation like Alaska, or many parts in rural America where you receive your drugs by mail? How do we work to ensure, not only the safety and the quality—which of course, we want to do and make sure that the FDA is regulating appropriately—but really to allow for a level of access to people in rural America?

I will throw it out to any of you. Dr. Anderson.

Mr. ANDERSON. We are working and getting a lot of mail order activities in the drug system. In most of the places in Alaska, if Federal Express gets there, your pharmaceuticals do.

Senator MURKOWSKI. No Federal Express in a village.

Mr. ANDERSON. No, I understand that.

Senator MURKOWSKI. Yes.

Mr. ANDERSON. But in many places.

Senator MURKOWSKI. They would like it.

Mr. ANDERSON. Exactly. But in many places it is, in fact, available and they are.

The delivery system is working very well in the system. Maybe not in the villages in Alaska, but in most parts of the United States, the distribution system is working as long as if it is not a very limited distribution system, as Senator Collins and I were talking about earlier. I think that is it.

The cost increases that are occurring are not occurring in the distribution system. It is really in the cost of the BPM's.

Senator MURKOWSKI. Right.

Mr. ANDERSON. It is the cost of the basic pharmaceutical company. That is where the cost is. I do not think we are going to be talking a lot about distribution systems here.

Senator MURKOWSKI. Mr. Mendelson.

Mr. MENDELSON. I agree with the comments about home delivery that it is a vital aspect, and I do not think that is going to change, but we will see more and more of that as more benefit managers encourage those programs.

With respect to the importation issues and this dates back to when I was running OBM Health under the Clinton administration and that was also being proposed around that time. And talking about things that are cyclical, every 3, 4, or 5 years there is an example of a drug that comes in from outside our borders and really hurts somebody.

As a result, I know that Congress had essentially put a certification in front of the FDA Commissioner and said, "We need the Commissioner to certify." And it had Democrats and Republicans in those positions and to date, no one has been willing to certify to the safety of the importation program.

That does give me some level of pause in terms of essentially abandoning the protections that we have in this country that are tightly regulated, not only by the Federal Government, but also by States and essentially kind of adopting an external regulatory regimen.

Senator MURKOWSKI. Let me ask about the PBM's because you have raised that and it just seems that we have kind of a self-reinforcing spiral when it comes to certain drug costs.

First, you have new drugs and they cost more money, and that drives up the cost of insurance. Then in an effort to reduce the monthly insurance premiums, insurers offer this array of plans that expose patients to more out-of-pocket costs. Then PBM's can negotiate some sort of a discount from the manufacturer in exchange for certain concessions, but those savings, then, are not passed on to the patient buying the drug. Instead, those savings are already built in to the cost of the patient's insurance premium.

Somebody who has bought only the insurance that they can afford, cannot afford the steep price of the drug because the insurance has a co-pay or a high deductible. The higher the list price of the drug, the more of a discount, then, that the PBM can negotiate and the more money then that PBM earns.

It seems that you are incentivizing the pharmaceutical companies to set a list price that is nowhere close to the actual cost of the drug, even when the R and D factored in and the cycle starts over again.

What do we do? I understand that Dr. Anderson would either eliminate the rebates to PBM's and PDP's, or mandate transparency. How do we get out of this cycle that it clearly appears that we are in?

Mr. ANDERSON. What you want to do is pay the PBM a fee for their services. They are performing a very valuable service. What you do not want to do is pay them, give them a portion of that rebate because that gives them the incentive to raise the price.

Senator MURKOWSKI. Just a flat fee or—

Mr. ANDERSON. A flat fee or some kind of incentive payment, but not based upon the price of the drug. You take away that rebate incentive to do it. If they can negotiate a better price, they can get a bigger fee, but they do not get a rebate.

Senator MURKOWSKI. Got it.

Dr. Howard.

Mr. HOWARD. Some employers do just that. I forget what the exact numbers are off the top of my head. About half of large employers ask for 100 percent of the rebate to be passed through to them, so they capture the full value of that, and then the PBM can be paid on a per member, flat fee basis. You can ask the other 50 percent of the employers who do not do that, why they do not do that.

I just wanted to draw attention to some innovative approaches on the payment end.

There was a study that United Health is trying to replicate where they tried to bundle physician payment services for cancer medicines, and for cancer care that physician delivered in the hospital.

In a nutshell, they found that drug costs went up by, I think, 136, 139 percent. But total healthcare costs for treating those cancers fell by 36 percent because the physician had an incentive to use a regimen at their own discretion that they felt would prevent other complications, prevent hospitalizations. They are trying to duplicate that experiment.

That is one way of putting the medicine at the center of a better outcome that can lower total cost and still force the manufacturers to demonstrate how they are impacting that outcome.

Senator MURKOWSKI. Thank you, Mr. Chairman.

Senator CASSIDY. Dr. Howard said they put the patient at the center of that, not the drug.

Mr. HOWARD. Correct.

Senator CASSIDY. Yes.

Senator Baldwin.

#### STATEMENT OF SENATOR BALDWIN

Senator BALDWIN. Thank you.

Mr. Chairman, Ranking Member, it is absolutely clear that we have a problem with drug prices when price increases accounted for 100 percent of the pharmaceutical industry's \$8.7 billion bump in earnings last year.

I fear that it is about to get even worse with the very partisan healthcare bill that is about to be brought to the Senate floor, which I believe will make many, many, many Americans pay a lot more for less care.

I am glad this is a bipartisan hearing. We should be working on bipartisan solutions to improve costs instead of pulling the rug out from under so many of our constituents, like my Wisconsin constituents, who are already struggling to pay for lifesaving medications.

Wisconsinites like Diane. Diane is from Webster, WI. She recently had to stop taking her Multiple Sclerosis medication that costs more \$90,000 annually today. She has seen the price increase over the last 23 years and she has seen her savings be just completely drained.

It is why I had the opportunity to introduce the Fair Drug Pricing Act with my colleague, Senator John McCain, to require basic transparency and accountability—like Research and Development costs, like marketing and advertising spending—for drug companies that choose to increase the price of certain drugs by more than 10 percent a year.

Holding drug companies accountable is a first step to addressing these dramatic price hikes that are making healthcare more and more unaffordable for too many families in Wisconsin.

I believe that the market is broken when people like Diane have to make that sort of decision and we continue to see these yearly price increases.

Pfizer has already raised the price of 90 of its existing drugs by about 20 percent this year. While drug companies often argue that their price hikes are due to product improvements, and new R and D, we have absolutely no way to verify this.

What could we do to limit these price increases for existing drugs? Do we need more information surrounding drug company pricing decisions to help improve access?

I want to start in answering that question with you, Mr. Coukell.

Mr. COUKELL. Thank you, Senator.

You started with Multiple Sclerosis, and it is an interesting area where there are a dozen drugs or so, and every time a new one comes along, the price of all the old ones go up. So that shows us that the market is not working the way markets are supposed to be working.

It is absolutely a difficult area to make policy in because there is such a lack of transparency about who is paying what. It is very, very complex.

I think the question of whether R and D costs have a direct relationship to price is an important one and clearly it is an expensive undertaking to develop a drug. But if two virtually identical drugs came to market with really different R and D costs, we would not expect them to have a different price.

Really as the consumer, what I want to buy is a clinical outcome, and it does not matter to me that much what the R and D cost is.

Senator BALDWIN. Thank you.

Mr. ANDERSON. Senator Baldwin.

Senator BALDWIN. I have a separate question for you, Dr. Anderson.

Since 2002, three major drug companies have increased the price of insulin by more than 200 percent. I heard from a constituent—his name is Greg from Stoddard, WI—who has two sons and is struggling to afford the costs of their diabetes and insulin treatment that costs more than \$1,000 a month.

I want to know if the drug maker that increases their price every year considers Greg's sons or any of the other families who depend on their drugs to function?

Dr. Anderson, can you discuss why companies who make life-saving drugs are incentivized to regularly increase their price or launch new drugs at radically high prices? How much does the impact of these high prices on real patients factor into any of their decisions?

Mr. ANDERSON. I had the opportunity to go to meet with the investment bankers and the drug companies, and ask pretty much that same question.

The simple answer is because they can.

Essentially, there is no regulation and because they have a monopoly, they can set the price at whatever they want to set it. So they essentially have that ability.

What they have seen from people like Martin Shkreli, who have done it and gotten away with it, that they should be able to do it. The investment bankers are often telling them, "You should do the same thing as Martin Shkreli did."

Senator CASSIDY. Senator Warren.

#### STATEMENT OF SENATOR WARREN

Senator WARREN. Thank you, Mr. Chairman.

I am glad we are having a hearing to talk about the skyrocketing price of prescription drugs. It is obviously a massive problem and there are a lot of different things we could do to help.

Senator Franken and I have a bill with a whole group of Senators that has a whole menu of options in it.

Senator Sanders and I have a bill with a group of Senators to allow medicines to be imported, cheaper medicines to be imported from Canada. Those are things we should be talking about.

Let us be blunt. It is insane to pretend to have a bipartisan hearing on lowering drug prices when right now, today, 13 Republicans are writing a secret bill to kick 23 million people off health insur-

ance and their prescription drug benefits, and we cannot even get a look at it.

Let us start there. Dr. Anderson, you are an expert in health policy. Before the Affordable Care Act, if you bought a plan on an individual market, did it have to cover prescription drugs?

Mr. ANDERSON. It did not.

Senator WARREN. It did not. And now the ACA requires that plans sold on exchanges cover prescription drugs as essential health benefits. Is that right?

Mr. ANDERSON. Yes, they are essential health benefits written into the law.

Senator WARREN. Yes. All right. Let us talk about a second part.

Before the ACA, insurance plans could also impose annual and lifetime limits, meaning that once patients had run up prescription drug costs to a certain point, the patient, not the insurer, would be on the hook for all the prescription costs after that. Is that right?

Mr. ANDERSON. Absolutely. People were being thrown into bankruptcy court as a result.

Senator WARREN. Let us talk about potentially who gets especially hurt.

How did those out-of-pocket costs hurt someone with a disability or a chronic illness?

Mr. ANDERSON. Well, they are the people that are taking the most drugs. If you have five or more chronic conditions, which is about 5 million Medicare beneficiaries, you are filling a prescription every week and that is just exceedingly expensive.

Senator WARREN. Before we had the ACA, we lived in a world where insurance stopped for those who needed it most and stopped whenever anyone needed it most.

I know the ACA's coverage of prescription drugs is not perfect, but if the secret Republican plan is anything close to the House bill, then millions of Americans will lose their access to prescriptions. The Republican plan will also gut Medicaid, which means millions more will not get access to their medicine.

In fact, I want to ask about Medicaid for a just a second.

While the Federal Government pays for prescriptions through a lot of different Federal programs, the best deal is Medicaid. A 2014 GAO study found that TRICARE paid 34 percent more than Medicaid for brand name drugs. Medicare Part D paid 69 percent more.

There are a lot of ways that we could lower drug prices. We could negotiate with Medicare, let Medicare negotiate. We could import cheaper medicines. And instead, the Republicans are talking about slashing the one Government program that does a good job of keeping prescription drug costs low.

My question goes in the other direction. Mr. Chairman, I assume that you have seen the bill, and I am not asking for details on this. Can we get some general outlines of the Republican plan? Will the secret Republican bill let insurance companies go ahead and drop prescription drug coverage or kick people off Medicare?

Senator CASSIDY. Senator Warren, I cannot answer that.

Senator WARREN. I appreciate that and you have been someone who has really tried to work in a bipartisan way on this issue.

This is just enormously frustrating. We are in here to talk about the importance of access to prescription drugs and the need to

bring down the costs, at the same time that 13 people are negotiating in secret to take away prescription drug coverage from millions of Americans.

There are people who want to be able to work in a bipartisan way. We have had our differences on this committee with Chairman Alexander and with others, but we try to sit down and work in a bipartisan way.

We cannot work in a bipartisan way if we cannot see the bill.

What is happening right now to deny Democrats and the rest of the Republicans access to this bill so that we can see the details, so that we can debate them out in public, so that we can have experts review them, so the American people can see them.

To deny the opportunity to see any of that is just flat wrong. In fact, it is shameful.

That is it for me, Mr. Chairman.

Senator CASSIDY. Briefly, Senator Baldwin.

Senator BALDWIN. Mr. Chairman, I want to request that testimony from the Campaign for Sustainable Prescription Drug Pricing be submitted for the record.

Senator CASSIDY. Without objection.

[The information referred to may be found in Additional Material.]

Senator CASSIDY. Senator Hassan.

#### STATEMENT OF SENATOR HASSAN

Senator HASSAN. Thank you, Mr. Chair and Ranking Member Murray.

As is true for all of my colleagues, I think the topic of today's hearing is incredibly important, and I appreciate the chance to discuss it.

I would venture to guess that just about every Member of Congress has heard from their constituents about the rising cost of prescription drugs. I hear about it from Granite Staters all the time.

I also right now, am hearing from Granite Staters all the time about Trumpcare and what the Senate is doing with Trumpcare.

Mr. Chair, I come from a State with a large citizen legislature, 424 volunteer legislators, where every single bill is required to get a hearing. You cannot pass legislation in New Hampshire if the bill has not had a hearing.

I am new to DC, but I continue to be amazed that we would not talk about a bill that impacts so many people and one-sixth of our economy. We hear references to it in the press. We know it is being worked on in secret, but we do not have even an outline of that bill for us to be able to examine ourselves or to get feedback from our constituents about which is what the other purpose of having hearings is about, so people can see it and they talk to us about it.

I appreciate this expert panel so much. But we have been talking today about the nuances of benefit plan design when, in fact, if Trumpcare passes, a whole lot of our constituents may not have a plan to begin with.

I join with my colleagues in being so frustrated that we are needing to spend time today when we want to be talking about the very important issue of access to lifesaving prescription medications for

our constituents. But we need to be talking about Trumpcare because if Trumpcare passes in anything near the form that the House bill is in, and we are told that the Senate plan is similar to the House bill, this will be kind of an academic discussion for a whole lot of our constituents.

I will join with my colleagues in asking the majority party to please share their plan with us, and to please include us, and to have a hearing so that our country can collaborate, and come together, and find a way forward.

One of the things that I am also very concerned about is that we are hearing that the Trumpcare plan will cut Medicaid. I think a lot about the people who are covered by Medicaid in my State with long term disabilities, who do not have the physical capacity to actually take the medicine themselves. We need nurses, and licensed nursing assistants, and homecare workers who can actually help. If Medicaid is slashed again, access to prescription drug medicine for a lot of our constituents is an academic issue if there is not somebody who can help them take it.

That is what I think we should be talking about in a companion hearing to this one—the overall Trumpcare bill.

I do have a couple of questions about some fundamental issues that affect drug pricing because, again, I appreciate the discussion about benefit plan design, but we are still talking about underlying costs that keep rising very quickly.

As you know, and Dr. Anderson, we began to talk about this in one line of questioning. Drug manufacturers often point to high research and development costs to justify high drug prices.

In December, Health and Human Services released a report that concluded drug manufacturers set prices to maximize profits. This finding is obvious, especially for those who struggle every day to afford their medications. But I want to point out something from this report that I find interesting and would ask for you to comment on it.

The HHS report said that the relationship between research and development costs and drug prices is subject to a number of misconceptions. In reality, the prices charged for drugs are unrelated to the development cost. Drug manufacturers set prices to maximize profits. At the time of marketing, R and D costs have already occurred and do not affect the calculation of a profit-maximizing price.

Dr. Anderson, your testimony echoes this finding. I really am curious to find out from you, as an expert in this field, do companies spend more on research and development or on marketing, advertising, and then add to it in the profits they take?

Mr. ANDERSON. Thank you for that question.

They spend less on research, and more on marketing and sales than most of the companies. Essentially, you are correct that there is no typical relationship between the amount invested in a particular drug and the price of that drug.

Overall, the companies need the money for R and D, but they do not actually price on the basis of how much R and D they put in to a particular drug.

Senator HASSAN. Thank you very much for your answer.

Thank you, Mr. Chair.

Senator CASSIDY. Senator Murphy.

STATEMENT OF SENATOR MURPHY

Senator MURPHY. Thank you very much, Mr. Chairman.

My apologies to the panel; I am not going to ask them any questions. I am not. I think this is a really interesting discussion, but I think it is totally irrelevant to the most important discussion that is happening right now, which is not in this committee. It is not anywhere that the American public can see.

It is behind closed doors where there are a certain number of Republican Senators that are perpetuating a fraud on the American public and they are not here. I mean, Democrats have been here at this hearing pretty consistently throughout the morning. Republicans have been in and out.

If you want to believe the Republicans are behind closed doors writing a healthcare bill that is going to steal insurance from 23 million American in order to pass along a tax cut to the richest amongst us. Then this visual is evidence, potentially, of what is going on right now.

Senator Hassan has it perfect. We can talk all we want about benefit design, but if 23 million Americans lose their access to health insurance, then they cannot afford prescription drugs. So it does not really matter what we do with respect to adjusting the intellectual property laws, or trying to differently regulate PBM's.

If there is a massive fall off of the number of people who have insurance, then nobody can afford the drugs that we are talking about here today. With all due respect to the chairman, not the chairman who is sitting there today, but the Chairman who made opening remarks, what does it matter that the bill was passed in 2009 in the middle of a snowstorm? What does it matter what the weather was outside?

There were 25 days of debate in the U.S. Senate before that bill came up for a vote. The American people had a month to watch the Senate debate that piece of legislation and offer amendments. And as the Ranking Member said that was on top of exhaustive committee processes.

It is just not true that that bill was rammed through. That is not true. The House and the Senate debated that bill for a year and a half. It was there for the American public to see.

The reason that we are watching this process play out in secret, the reason why no one in this country will see this piece of legislation until it is already passed is because Republicans learned a lesson from 2009 and 2010. That it did not accrue to Democrats' benefit to have that process play out over such a long period of time, so that is why they are going to keep this secret.

They are going to keep it secret because inside that bill are massive giveaways for their friends. \$145 billion of tax breaks for health insurers. \$28 billion of tax breaks for pharmaceutical companies. \$663 billion of tax cuts, almost none of which is going to anyone in this country who makes under \$200,000 a year.

There is good reason why there are no Republican Senators here except for Senator Cassidy. There is good reason why they are doing this behind closed doors because it is a fraud.

It is a fraud to take insurance from middle class folks, folks who might be struggling in this country so that you can muster up enough money to hand another big tax break to people that do not need it.

I hope eventually we can sit down and have a conversation about drug pricing that is meaningful and relevant, but this is not. This is just a distraction from what the real story is, which is this committee becoming irrelevant as a secret process unfolds to radically change one-sixth of the American economy.

Senator CASSIDY. Senator Sanders.

#### STATEMENT OF SENATOR SANDERS

Senator SANDERS. Thank you very much, Mr. Chairman.

I want to talk about prescription drugs, but I want to concur with Senator Murphy, and Senator Murray, and I suspect others. We are talking about one-sixth of the American economy and there will be no public discussion. No committee hearings. No witnesses coming forward. This is really outrageous.

I want to focus on an issue which is also outrageous and that is I am hearing from my constituents in Vermont—that I suspect every other Senator here is hearing from his or her constituents back home—that they are sick and tired of being ripped off by the pharmaceutical industry, and they are very tired of paying by far the highest prices in the world for prescription drugs.

At a time when drug prices are soaring, millions of Americans are unable to afford the medicine they need. This is the United States of America, approximately one out of five Americans under the age of 64 who gets a prescription from a doctor cannot afford to fill that prescription.

How many of those people die? We do not know.

How many of those people suffer, become much sicker than they should have been? We do not know.

How much cost occurs when people end up in the hospital because they did not take medicine when they should have? We do not know, but clearly it is many billions of dollars.

Mr. Chairman, there is no rational reason why in the United States, Gleevec, which is used to treat leukemia, costs over \$10,000 in our country, but \$2,100 in Norway.

Why does a drug called Lantus, a diabetes drug, cost \$186 in America, but \$47 in France?

Why does Crestor, a popular drug for high cholesterol, cost \$86 in the United States, and \$29 in Japan?

Why does Advair, used to treat asthma, cost \$155 in the United States, \$38 in Germany? On and on and on it goes. We are not just picking these drugs out. That is all across the board. Some cases the discrepancy is more, some it is less.

Without exception, we pay the highest prices in the world for prescription drugs. Why is that? That really should be the simple question that is debated today, and I apologize. I have been to other hearings and I hope it has been discussed, but that is the question.

Why in this country do we pay the highest prices in the world compared to every other country on earth? The answer is simple. Follow the money.

Since 1998, the pharmaceutical industry has spent more than \$3 billion in lobbying. This is not some kind of high technical, medical issue. Three billion dollars in lobbying and they have spent hundreds of millions of dollars on campaign contributions.

We have a corrupt campaign finance system. We have a corrupt lobbying system. The reason we pay the highest prices in the world is an example of that for prescription drugs.

An incredible example, last year—I was involved in this—people of California wanted lower prescription drug costs. The drug companies spent \$131 million in one State to prevent the people of California from lowering drug prices in their own State.

Meanwhile, while Americans are dying because they cannot afford the medications they need, the five largest drug companies in the country made over \$50 billion in profits in 2015, while the top 10 pharmaceutical industry CEO's made \$327 million in total compensation.

This is not a complicated issue. The drug companies are enormously powerful. They own much of the U.S. Congress. They make outrageous profits. Their CEO's earn outrageous levels of compensation, and yet back in Vermont, we have elderly seniors cutting their pills in half because they cannot afford the price.

There are a number of solutions to this problem. They are fairly obvious. They have been discussed here for a long, long time. The real issue is whether the Congress has the guts to take on the very powerful pharmaceutical industry. I must say, there is not any particular evidence to believe that that will occur.

What we need right now in this country are people from coast to coast standing up and fighting back for their own health, for the health of their children, for the health of their parents. Demand support for legislation like drug re-importation.

My colleague, Senator Franken, has issued a very good, comprehensive piece of legislation and other people have demanded that Medicare, for example, start negotiating prices with the pharmaceutical industry.

There are a lot of things that we can do. We know what the answers are. The question is, will the Congress have the guts to stand up to one of the most powerful political forces in the United States of America? That is the pharmaceutical industry.

Thank you.

Senator CASSIDY. Senator Whitehouse.

#### STATEMENT OF SENATOR WHITEHOUSE

Senator WHITEHOUSE. Thank you, Chairman.

I can remember once when our Republican colleagues were so sensitive to regular order in the Senate that they were accusing the Affordable Care Act of being a cooked up, closed door deal even when that was not even true.

We had in this committee, in this very committee, 47 bipartisan hearings, meetings, roundtables, and/or sessions. We considered 300 amendments. There were 160 Republican amendments adopted. We sat in that big conference room day, after day, after day going through huge stacks of amendments.

It looks like what is going to happen here is that the majority leader is going to call up the wretched House bill on the floor. If

there is an amendment process, it will be a sham because all amendments will be stripped out because he will offer a complete replacement, which will be the secret Senate bill, the first chance anybody will have to see it.

No amendments will then be in order and they will cram it through on a fixed vote with only then the secret CBO score being provided. Then they will go off to conference with the House, which did the original wretched bill. It will obviously get even worse in conference with the House.

That may be the most disgraceful Senate process in the history of this body and it is certainly a closed door deal that bears no comparison to the open, robust process by which we got to the Affordable Care Act. Let me just make that point.

Let me ask the panel, where there is, in fact, competition among pharmaceuticals, how does the market tend to work?

Mr. ANDERSON. There are two answers to your question.

Senator WHITEHOUSE. Make it quick.

Mr. ANDERSON. When there is generic competition with a lot of competitors, it works incredibly well.

Senator WHITEHOUSE. OK. Next. Howard.

Mr. HOWARD. When there are close therapeutic substitutes, the drugs are very similar, rebates are very large and the competition is fierce.

Senator WHITEHOUSE. Mr. Coukell.

Mr. COUKELL. I agree.

Mr. MENDELSON. Agree.

Senator WHITEHOUSE. OK. When there is real competition, it tends to work.

Next question, how hard is it to determine when a drug pricing monopoly exists for people who have some familiarity with this market? Is this, like, a really impossible thing to figure out?

On a scale of 0 to 10, how hard is it to figure out that a drug enjoys an effective pricing monopoly?

Mr. COUKELL. All brand drugs enjoy a pricing monopoly. Some have competition from other products. It is a little harder to tell when a generic has a monopoly, when it is the only product in the market, but not impossible.

Senator WHITEHOUSE. You can tell. There are some drugs that clearly do have a monopoly where monopoly rents can be extracted. Correct?

Mr. COUKELL. Yes.

Senator WHITEHOUSE. And that is visible. People can see that.

Mr. COUKELL. Yes.

Senator WHITEHOUSE. Yes? Economists can look at it and say yes, that is monopolistic behavior. Correct?

Mr. COUKELL. Correct.

Senator WHITEHOUSE. Correct. OK.

What do we do as a country when we see that monopolistic behavior? Who steps in at that point and says, "But wait a minute. That is actually an effective monopoly. We are going to have to do something about this pricing."

Long pause because nobody does.

That takes me to Senator Sanders' point. As Senator Baldwin mentioned, the Credit Suisse just found that price increases have

added \$8.7 billion in net income to the companies that they analyzed; \$8.7 billion in added net income.

Also, we have this wretched decision called Citizens United, which allows industries to come in and spend unlimited amounts of money on influence in Congress.

If you are making an extra \$8.7 billion, how much money might it make sense to spend to try to exert influence in Congress? The answer is probably around \$8.7 billion. Of course, they do not need to spend that much because we tend to come cheaper than that.

It is impossible to imagine that we could not solve, in good faith, the pharmaceutical pricing problem, or at least take a good whack at it in this country, in a week if it were not for the special influence operations that control the Senate and control the House.

It is not just the unlimited money that we see spent. Once Citizens United let the pharmaceutical industry, and the fossil fuel industry, and the other big players here spend unlimited amounts of money. That also allowed them to go to the dark money channels and blow them out so that they could spend unlimited dark money so that you do not even see their hands in operation.

I associate myself with the comments of Senator Murphy, Senator Baldwin, Senator Sanders, and Senator Murray. This is a solvable problem except for the fact that we are too in tow to big special interests.

Look out for the special interest prizes buried in the secret Senate Republican healthcare bill.

Senator CASSIDY. Senator Franken, second set of questions.

Senator FRANKEN. Thank you, Mr. Chairman.

Let me speak to what my colleagues have been speaking to, which is this Republican process that is going on behind closed doors.

There is a hope here, which is that they need 50 votes. And there is the hope that enough of my Republican colleagues do not vote for a bill that will hurt the American people. These are colleagues. They are colleagues on the other side of the aisle, the acting chairman among them, who cares about patients, who has run a clinic for patients who are in need.

There is hope that there are enough colleagues on the other side of the aisle that will not allow something to get passed that will hurt the American people and that will make this discussion completely moot.

I am here because I go around the State of Minnesota, and everyone knows that the prices of pharmaceuticals have shot up in the last 3 years, and they are feeling it.

We have you four here, and I want to use your expertise to talk about that, and put aside this process that none of us, on this side, anyway, like—and I suspect that many on the other side do not like—and use the fact that you are here.

I hope we do have a roundtable with you and I hope we can do it under maybe different circumstances where we are not talking just at the margins. We are talking about something that is very key to the American people and not just on the margins considering something very bad getting passed.

I want to ask you about this idea of the R and D costs. I have heard some testimony from both Mr. Coukell and Dr. Anderson

about the R and D. Very often it is said, "Well, you have got to let them charge this much because otherwise they would not be able to develop drugs."

This is what an article recently published in the *Journal of American Medical Association* said,

"Although prices are often justified by the high costs of drug development, there is no evidence of an association between research and development costs, and prices. Rather, prescription drugs are priced in the United State primarily on the basis of what the market will bear."

Do you think JAMA is correct?

Mr. COUKELL. Senator, one of the areas we work on is antibiotics. It is really hard to make money on antibiotics because when a new one comes to market, it is competing with old ones that are really cheap. And so that goes to show you that it is not related directly to the R and D costs. It is related to what the market is willing to pay based on the outcomes you get.

Mr. HOWARD. To put that in a slightly different way, so that returns on investment are very sensitive to the prices that drugs command. So that when there is an attractive environment for investment, more money goes into R and D.

There has been a great deal of econometric work from RAND and other places that shows when those returns decline, money going into R and D can decline as well.

The problem is that investors have alternatives. If they can look at getting the next Snapchat or pick your favorite Web application that they can make a billion dollars on in a few years and not face regulatory approval compared to a product that performs at term.

Senator FRANKEN. Let me ask to that end. What are the profit margins of pharmaceutical companies versus, say, other sectors in the economy, say steel?

Mr. HOWARD. The CBO has found that returns on investment for the industry are comparable to other high tech industries.

Senator FRANKEN. Other high tech. OK. I said steel. You did not answer my question.

Mr. HOWARD. Should we compare them to donuts? We should compare them to other high R and D industries.

Senator FRANKEN. You should answer my question first.

Mr. HOWARD. Right. There are lower returns for commodity-based industries like steel than there are to other returns like software where there are important I.P. protections and higher returns as well.

Senator FRANKEN. At least that was an answer. Thank you. I appreciate that.

I am out of time, but there are so many—can I make a couple of points?

Senator CASSIDY. If you can make them quickly, because I have to head out.

Senator FRANKEN. We should be able to import from Canada. We should be able to have a safe path and I think we also pay with NIH funding; I do not think that is talked about enough. We should negotiate within Medicare Part D.

I would like to get that roundtable, so we can discuss all that again.

Dr. Howard, thank you again for your answer.

Thank you.

Senator CASSIDY. Senator Murray.

Senator MURRAY. Thanks very much, Mr. Chairman.

I want to thank all of our witnesses. This is an important hearing. It is a hearing about a cost to American families that is dramatically growing that they are deeply concerned about. We do need to figure out a way to proceed forward in a bipartisan way.

Mr. Chairman, thank you for your forbearance and patience. I know you want to go crash the secret meeting, so I do not want to hold you up too much longer.

Senator MURRAY. Can I come with you and crash that meeting? Because I will tell you, people across the country want to know what is in it because the cost of healthcare is critical to every family, every business, every community, everyone.

The fact that a Republican Trumpcare bill is going to be jammed through here in a few weeks without any look at it by this committee, to me, is really appalling.

We have a responsibility to our constituents to ask questions, to offer amendments, to be a part of that process particularly when millions of Americans are going to lose their coverage, pay higher costs, and feel the impact of that.

I know you want to get to the meeting. I appreciate that. I will just say we are really appalled that this is being done in secret, and I hope you pass that onto your colleagues.

Thank you very much.

Senator CASSIDY. I will also thank you and what I kind of draw from our meeting today is that there is a tension between how do we drive innovative for that antibiotic, for example, and how do we keep drugs affordable?

Dr. Howard, your point at the end—about drug company profits are comparable to other high tech R and D—is appropriate. We cannot ignore the fact that some people cannot access drugs.

Also my own concern, but I think I heard it here, is that we are driving some patients into the catastrophic portion of Medicare Part D which is really increasing the bill for the Federal taxpayer as well as for that person who is not getting that point of sale rebate.

Two more things we heard. We need to leverage outcomes data to identify and reward value. Last, the whole process is opaque, so pity the poor patient who is trying to make a sense of it. So if we can get transparency, That could help.

Let me finish by saying the hearing record will remain open for 10 days. Members may submit additional information for the record within that time should they wish.

Thanks again for being here.

The committee stands adjourned.

[Additional Material follow.]

## ADDITIONAL MATERIAL

### PREPARED STATEMENT OF JOHN ROTHER, EXECUTIVE DIRECTOR, THE CAMPAIGN FOR SUSTAINABLE RX PRICING (CSRxP)

Chairman Alexander, Ranking Member Murray, and members of the Senate HELP Committee, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on the critically important issue of unsustainable growth in prescription drug prices.

CSRxP is a project of the National Coalition on Health Care Action Fund. We are nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that improve affordability while maintaining access to prescription drugs for American patients and their families. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and health plans.

We look forward to continuing our work with the committee to address the unsustainable growth in prescription drug prices, which can threaten the financial security, health and well-being of American patients and their families. Below we describe how the current marketplace enables the brand pharmaceutical industry to engage in anti-competitive practices that drive up prescription drug prices for consumers and present market-based, bipartisan solutions that would allow U.S. patients to continue to access the medicines they need at prices more affordable than currently available to them.

#### I. SPENDING GROWTH ON PRESCRIPTION DRUGS FAR EXCEEDS SPENDING GROWTH IN THE U.S. HEALTHCARE SECTOR MORE BROADLY

U.S. spending on prescription drugs is unsustainable and growing at a rate faster than the rest of the healthcare sector. In 2015, for example, while overall growth in U.S. healthcare spending increased by 5.8 percent, growth in spending on prescription drugs increased by 9 percent and outpaced spending on all other medical services.<sup>1</sup> Medicare has followed a similar trend in recent years, as spending growth on drugs has exceeded spending growth in other parts of the program. The Medicare Trustees stated in their 2016 report, for example, that per capita drug spending in Part D grew faster than historical rates in 2015, driven in large part by continued growth in prescription drug prices and a “surge” in spending on expensive specialty medicines, and they project such accelerated growth will continue in the future for similar reasons.<sup>2</sup> Likewise, Medicare Part B spending on prescription drugs increased at a rapid average annual rate of 7.7 percent from 2005 to 2014; during that period, specialty biologic medicines grew at a particularly fast rate, increasing from 39 percent to 62 percent of total spending, with a significant share of the growth due to price increases rather than number of patients using the medications.<sup>3</sup>

#### II. THE BRAND PHARMACEUTICAL INDUSTRY IS DRIVING EXCESSIVE DRUG COST GROWTH BY SETTING NEEDLESSLY HIGH LIST PRICES FOR ITS PRODUCTS AND INCREASING THOSE PRICES BY AMOUNTS THAT SUBSTANTIALLY EXCEED INFLATION AFTER THEY ENTER THE MARKET.

Despite efforts from the brand name drug industry to suggest otherwise, the pharmaceutical industry is the primary driver of the unsustainable and needless growth in prescription drug costs that American patients and their families face today. The industry sets high initial prices for its products and consistently increases those prices at rates that typically exceed inflation.

The brand pharmaceutical industry acknowledges that the list prices it sets represent the majority of the cost that U.S. patients pay out-of-pocket for their prescription drugs. “More than half of what commercially insured patients pay out-of-pocket for brand medicines is based on the list price,” the Pharmaceutical Research

<sup>1</sup>Centers for Medicare and Medicaid Services. “NHE Fact Sheet.” See link: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html>.

<sup>2</sup>2016 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, page 108. See link: <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/tr2016.pdf>.

<sup>3</sup>HHS Assistant Secretary for Planning and Evaluation. “Medicare Part B Drugs: Pricing and Incentives,” page 6. March 8, 2016. See link: <https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf>.

& Manufacturers of America States.<sup>4</sup> In other words, the industry alone sets the lists price that comprises a majority of the patient's out-of-pocket spending, meaning that the brand drug industry has significant control over the excessive and unsustainable costs that U.S. patients and their families bear in purchasing prescription drugs.

Indeed, the brand industry today is using its ability to set high list prices for its products—and add to the already unwarranted costs consumers pay out-of-pocket for the prescription medications they need. One recent analysis found, for example, that list prices for prescription drugs grew 9.8 percent in 2016 after a 10.8 percent increase in 2015.<sup>5</sup> By way of comparison, the CPI increased by 2.1 percent and 0.7 percent, respectively, in 2016 and 2015.<sup>6</sup>

The industry also acknowledges the important role that pharmacy benefit managers, wholesalers, pharmacies and other intermediaries play in reducing the list price by negotiating discounts and rebates off that list price, thereby lowering overall cost of medicines for U.S. consumers. However, brand drug makers find ways to keep costs unsustainably high even after these discounts and rebates are negotiated for consumers by implementing excessive price increases that typically exceed inflation after a product enters the market.

AARP found, for instance, that retail prices increased in 2015 for 97 percent of the widely used brand name prescription drugs and all of these increases exceeded the rate of general inflation that year.<sup>7</sup> Another study showed that prices for 4 of the 10 top-selling drugs in the United States increased by more than 100 percent between 2011 and 2014 and for 6 of the 10 top-selling drugs in the United States grew by more than 50 percent during that same period.<sup>8</sup> The trend appears to be continuing in 2017, as another analysis determined that there were 40 drug price increases in the first quarter of 2017—up from 33 in 2016.<sup>9</sup>

Manufacturers of expensive specialty medications, in particular, significantly contribute to this critical problem of unsustainably high list prices and price increases in excess of inflation. AARP determined, for example, that the average cost of a specialty medication in the United States was \$53,000 in 2013.<sup>10</sup> In that year, that amount was more than: (1) The average annual U.S. household income—\$52,250; (2) two times the median income of a Medicare beneficiary—\$23,500; and (3) three times the average Social Security retirement benefit—\$15,526.<sup>11</sup>

Within specialty medicines, one area of particularly significant concern is the treatment of patients with cancer. In the United States, a novel anti-cancer drug routinely costs more than \$100,000 per year or course of treatment and the median launch price of a new oncology drug has increased in each decade from the 1960s to today from \$100 to \$10,000 per month of treatment.<sup>12</sup> Similarly, a separate analysis demonstrated that the inflation-adjusted price of an anti-cancer medicine often increases after launch, by as much as 44 percent over the course of the decade.<sup>13</sup> These rapidly growing and excessive oncology drug costs represent potentially sig-

<sup>4</sup>Pharmaceutical Research & Manufacturers of America. "More Than Half of Patients' Out-of-Pocket Spending for Brand Medicines Is Based on List Price." March 27, 2017. See link: <http://www.phrma.org/graphic/more-than-half-of-patients-out-of-pocket-spending-for-brand-medicines-is-based-on-list-price>.

<sup>5</sup>Saganowsky, Eric. "Report: Price Hikes Are Still Driving Pharma's Earnings Growth. Who's Most At Risk?" *Fierce Pharma*. April 19, 2017. See link: <http://www.fiercepharma.com/pharma/despite-scrutiny-price-hikes-still-driving-pharma-s-eps-growth-report>.

<sup>6</sup>Bureau of Labor Statistics. "CPI Detailed Report. Data for December 2016," page 2. See link: <https://www.bls.gov/cpi/cpid1612.pdf>.

<sup>7</sup>AARP Public Policy Institute. "Rx Price Watch Report: Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2015," page 10. December 2016. See link: <http://www.aarp.org/content/dam/aarp/ppi/2016-12/trends-in-retail-prices-dec-2016.pdf>.

<sup>8</sup>Humer, Caroline. "Exclusive: Makers Took Big Price Increases on Widely Used U.S. Drugs." *Reuters Health News*. April 5, 2016. See link: <http://www.reuters.com/article/us-usa-health-care-drugpricing-idUSKCN0X10TH>.

<sup>9</sup>Tirrell, Meg. "The Drug Industry Is Addicted to Price Increases, Report Shows." *CNBC*. April 20, 2017. See link: <http://www.cnn.com/2017/04/20/the-drug-industry-is-addicted-to-price-increases-report-shows.html>.

<sup>10</sup>AARP Public Policy Institute. "Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2013," page 8. November 2015. See link: <http://www.aarp.org/content/dam/aarp/ppi/2016-12/trends-in-retail-prices-dec-2016.pdf>.

<sup>11</sup>AARP Public Policy Institute. "Rx Price Watch Report: Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans, 2006 to 2015," page 1. February 2016. See link: <http://www.aarp.org/content/dam/aarp/ppi/2016-02/RX-Price-Watch-Trends-in-Retail-Prices-Prescription-Drugs-Widely-Used-by-Older-Americans.pdf>.

<sup>12</sup>Prasad, et. al. "The High Price of Anticancer Drugs: Origins, Implications, Barriers and Solutions." *Nature Reviews Clinical Oncology*. 2017. Advanced Online Publication, page 1.

<sup>13</sup>*Ibid.*

nificant barriers for patients in accessing lifesaving and life-sustaining treatments who simply may not be able to afford them.

In analyzing this extreme and rapid growth in cancer drug costs, researchers emphasized how these costs both hurts patients, who in many cases may not be able to afford these expensive medications, and society at large, which simply will not be able to financially bear the unsustainable burden of excess drug cost growth over the long-term:

“Not only are launch prices high and rising, but individual drug prices are often escalated during exclusivity periods. High drug prices harm patients—often directly through increased out-of-pocket expenses, which reduce levels of patient compliance and lead to unfavorable outcomes—and harms society—by imposing cumulative price burdens that are unsustainable.”<sup>14</sup>

### III. DRUG MANUFACTURERS SUGGEST THAT RESEARCH AND DEVELOPMENT JUSTIFIES HIGH DRUG PRICES—BUT DATA SHOW THAT THE EXCESSIVE AMOUNTS CHARGED TO U.S. PATIENTS IN AGGREGATE EXCEED THE INDUSTRY’S GLOBAL R&D BUDGET

A recent analysis concluded that the drug prices paid by U.S. consumers create significantly more revenue for the brand pharmaceutical industry than the amount the industry expends *globally* on research and development. Specifically, the analysis found that 15 drug companies that manufactured the 20 best-selling drugs worldwide in 2015 made \$116 billion in excess revenue from U.S. drug prices.<sup>15 16</sup> Meanwhile, brand drug makers only spent \$76 billion—or \$40 billion less—on global research and development that same year.<sup>17</sup> As one author of the analysis Dr. Peter Bach, director of Memorial Sloan Kettering Cancer Center’s Center for Health Policy and Outcomes, clearly said: “the math doesn’t work out.”<sup>18</sup>

Moreover, brand drugs with the highest prices sometimes are the ones that are the least costly to develop, indicating that a drug maker’s R&D budget does not necessarily justify the setting of high drug prices or excessive price increases. In other words, as one recent study found, high prices do not necessarily correlate with the innovative R&D that the pharmaceutical industry maintains it is supporting in part through excessive drug cost growth.<sup>19</sup> Specifically, the study explains that the

“costliest drugs to develop are those which require large phase III clinical trials involving tens of thousands of patients, such as drugs for diabetes, high blood pressure, and heart disease. . . . But in fact, new drugs in these areas have little pricing power, because doctors have the ability to prescribe effective and inexpensive generics for these conditions.”<sup>20</sup>

By contrast, the

“cheapest drugs to develop are those which require small clinical trials involving dozens of patients, such as drugs for ultra-rare, or ‘ultra-orphan’ conditions. . . . Phase III trials for these conditions, which only affect several thousand people in the United States, run in the tens of millions. But manufacturers have generated billions in revenues from them.”<sup>21</sup>

### IV. EXCESSIVE DRUG PRICES PAID BY AMERICAN PATIENTS AND FAMILIES ENABLE THE DRUG INDUSTRY TO PAY FOR NEEDLESS ADVERTISING AND MARKETING—AND CONTRIBUTE TO DRUG MAKERS’ BOTTOM LINES

If the drug industry does not spend all of the money it receives from U.S. consumers on its products on R&D as shown above, the question arises as to where the industry actually spends those excessive revenues. It turns out that brand man-

<sup>14</sup> *Ibid.*

<sup>15</sup> Note that this study looked at net prices—not list prices—that U.S. consumers paid for prescription drugs. Net prices reflect discounts and rebates that pharmacy benefit managers, wholesalers, pharmacies, and other members of the supply chain negotiate with drug manufacturers to lower the list price initially set.

<sup>16</sup> Yu, Nancy et. al. “R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices.” *Health Affairs Blog*, March 7, 2017. See link: <http://healthaffairs.org/blog/2017/03/07/rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/>.

<sup>17</sup> *Ibid.*

<sup>18</sup> Sagonowsky, Eric. “High U.S. Drug Prices Cover Pharma’s Global R&D—And a Whole Lot More, Study Finds.” *Fierce Pharma*, March 10, 2017. See link: <http://www.fiercepharma.com/pharma/high-u-s-drug-costs-pay-for-pharma-s-global-r-d-plus-more-study-finds>.

<sup>19</sup> Roy, Avik. “The Competition Prescription: A Market-Based Plan for Making Innovative Medicines Affordable,” page 7. See link: <http://www.csrpxp.org/wp-content/uploads/2017/05/The-Competition-Prescription1.pdf>.

<sup>20</sup> *Ibid.*

<sup>21</sup> *Ibid.*

ufacturers are using a significant portion of those funds for marketing and advertising—and to increase their bottom lines.

First, many members of the brand drug industry spend more on advertising and marketing than R&D; one analysis determined that 9 of the 10 largest drug companies spent more on marketing than they did on research in 2013.<sup>22</sup> A separate analysis found that drug makers specifically are increasing their spending on television advertising in the United States, spending \$6.4 billion on TV consumer advertising in 2016—an increase of 5 percent over 2015 and of 62 percent since 2012.<sup>23</sup> Along those same lines, in 2016, drug advertising represented the sixth largest category of TV advertising, accounting for 8 percent of total TV advertising revenue and increasing six places from twelfth place in the category in 2012.<sup>24</sup>

Importantly, while drug makers suggest marketing and advertising help inform patients and their providers of treatment options, these industry tactics also drive up health care costs for all consumers—not just those that take prescription drugs. Television advertisements often induce unnecessary demand, encouraging patients and their families to ask physicians for drugs they may not need.<sup>25</sup> Similarly, drug makers' direct marketing to physicians informs prescribers about the availability of specific treatment options—and not necessarily those treatments that are the most effective and least costly for the patient. Both cases needlessly and unfairly increase healthcare costs for all Americans—not just those using prescription medicines—by unnecessarily increasing spending on prescription drugs overall, thereby driving up overall insurance premiums for all U.S. consumers.

Second, and very importantly, brand drug manufacturers depend on these unsustainable high drug prices to help support their bottom line growth; price increases now are replacing a decline in prescription volume that the industry is facing for at least certain types of medications. To this point, one recent analysis found that between 2011 and 2014, *sales* from the top 10 drugs increased 44 percent even though *prescriptions* for the medications decreased by 22 percent.<sup>26</sup> Likewise, another analysis determined that drug price increases contributed \$8.7 billion to net income for 28 companies analyzed, representing 100 percent of earnings growth for those companies in 2016.<sup>27</sup> Hence, it seems very unlikely that many brand drug makers have much incentive to curb the unsustainable and excessive drug price growth absent bipartisan action to change these unfair pricing practices that hurt American patients and their families.

#### VI. RULES EMBEDDED IN THE U.S. REGULATORY SYSTEM PERMIT THE BRAND DRUG INDUSTRY TO ENGAGE IN ANTI-COMPETITIVE PRACTICES THAT BLOCK AFFORDABLE GENERIC COMPETITION AND KEEP DRUG PRICES HIGH, DRIVING UP PRESCRIPTION DRUG COSTS FOR PATIENTS AND FAMILIES AND ALL U.S. CONSUMERS

The brand drug industry often manipulates the current U.S. regulatory system in an anti-competitive manner to limit and restrict patient access to the affordable medications they need.

First, the Orphan Drug Act introduced a range of incentives—most importantly 7 years of market exclusivity with no competition—to encourage the development of medications to treat rare diseases, or those diseases that affect fewer than 200,000 patients. Since passage of the Orphan Drug Act, hundreds of orphan drugs have been approved. Many of these medications are helping patients who previously had no treatment options.

However, an increasing number of orphan drugs have achieved blockbuster status, with billions of dollars in sales annually. Oftentimes in these cases, drug manufacturers have secured a single “orphan” indication for a drug's use and then, after FDA approval, patients use the drugs off-label far more broadly beyond that single indication use. In effect, manufacturers benefit from having the special orphan exclusivity period that restricts competition but allows their products to be used off-

<sup>22</sup> Swanson, Ana. “Big Pharmaceutical Companies Are Spending Far More on Marketing than Research.” *The Washington Post*. February 11, 2015. See link: [https://www.washingtonpost.com/news/wnk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm\\_term=.916fc28032c9](https://www.washingtonpost.com/news/wnk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.916fc28032c9).

<sup>23</sup> Appleby, Anne and Horovitz, Bruce. “Prescription Drug Costs Are Up; So Are TV Ads Promoting Them.” *The USA Today*. March 16, 2017. See link: <https://www.usatoday.com/story/money/2017/03/16/prescription-drug-costs-up-tv-ads/99203878/>.

<sup>24</sup> *Ibid.*  
<sup>25</sup> *Ibid.*

<sup>26</sup> Humer, Caroline. “Analysis: Drugmakers Take Big Price Increases on Popular Meds in U.S.” *Scientific American*. See link: <https://www.scientificamerican.com/article/analysis-drug-makers-take-big-price-increases-on-popular-meds-in-u-s/>.

<sup>27</sup> Tirrell, Meg. “The Drug Industry Is Addicted to Price Increases, Report Shows.” *CNBC*. April 20, 2017.

label for treatments of other types of disease—and oftentimes at very high prices for patients. To this point, a recent analysis found that 7 of the top 10 best-selling drugs in the United States in 2014 came on the market with an “orphan” designation.<sup>28</sup>

Second, brand name drug companies are using FDA regulations to engage in anti-competitive behavior that blocks competition of certain drugs that require additional safety protections. For specific drugs with specific safety risks, FDA requires manufacturers to develop detailed Risk Evaluation and Mitigation Strategies (REMS) prior to entering the market. While this type of information creates additional safety information for patients and offers safeguards for providers, brand drug manufacturers have manipulated REMS to block generic manufacturers from obtaining samples of brand drugs under the guise of addressing patient safety concerns. This practice restricts competition in the market and often leaves patients with fewer choices for their medications. As a result, patients may be at the mercy of a single drug company for the medication they need to stay healthy, and that company is free to set the price for that medication indiscriminately. This practice stifles the introduction of generic competition, thus preventing lower-priced options from being available to patients and increasing costs for everyone. Bipartisan legislation has been introduced in both the Senate and the House—the CREATES Act and the FAST Generics Act—that would stop this anticompetitive practice. We therefore encourage the committee to consider bipartisan legislation that addresses these abuses by prohibiting companies from restricting access to samples.

#### VII. MARKET-BASED SOLUTIONS CAN HELP REIN IN EXCESSIVE DRUG COST GROWTH FOR U.S. PATIENTS AND FAMILIES.

CSRxP supports adoption of bipartisan, market-based solutions to help curb the excessive and unsustainable growth in prescription drug spending for U.S. patients and their families. To that end, CSRxP strongly urges the committee to support and adopt the following policies that promote transparency, foster competition, and incentivize value in the marketplace, making drugs more affordable and accessible for the patients who need them.

##### 1. *Promote Transparency*

- **Drug manufacturers should release details of a drug’s unit price, cost of treatment, and projection on Federal spending before FDA approval.** Given the significant impact pharmaceuticals have on overall health care spending, manufacturers should be required to disclose information on the estimated unit price for the product, the cost of a course of treatment, and a projection of Federal spending on the product.

- Drug makers should annually report increases in a drug’s list price. Similar to requirements already in place for other entities like health plan issuers, hospitals and nursing facilities, pharmaceutical companies should report increases in drug’s list price. Furthermore, HHS should provide an annual report to the public that includes the top 50 price increases per year by branded or generic drugs; the top 50 drugs by annual spending and how much the government pays in total for these drugs; and historical price increases for common drugs, including those covered by Medicare Part B.

- **Manufacturers should disclose drug R&D costs.** Drug makers should be required to disclose how much drug research was funded by public entities like the National Institute of Health (NIH) or other academic entities or by other private companies, so that regulators and taxpayers can properly weigh return on investment.

We encourage the committee to consider bipartisan legislation, the FAIR Pricing Act, sponsored by Senators Baldwin and McCain that would bring great transparency to the pharmaceutical industry.

##### 2. *Foster Competition*

- **Speed FDA approval of generic drug applications—especially for life-saving drugs and for drugs with no or limited generic competition.** The FDA faces a backlog of nearly 4,000 generic drug applications, yet approval times can be 3 or more years. The FDA should receive the resources necessary to clear this backlog and prioritize generic drug approval applications, especially for lifesaving drugs and drugs with no or limited generic competition.

<sup>28</sup> “Orphan Drug’ Loophole Needs Closing, Johns Hopkins Researchers Say.” November 19, 2015. See link: [http://www.hopkinsmedicine.org/news/media/releases/orphan\\_drug\\_loophole\\_needs\\_closing\\_johns\\_hopkins\\_researchers\\_say](http://www.hopkinsmedicine.org/news/media/releases/orphan_drug_loophole_needs_closing_johns_hopkins_researchers_say).

- **Reduce drug monopolies by incentivizing competition for additional market entrants.** Several FDA programs are intended to expedite review of new drugs that address unmet medical needs for serious or life-threatening conditions. Incentives should drive competition for expensive treatments where no competitors exist and encourage a second or third market entrant.

- **Strengthen post-market clinical trials and surveillance.** Currently, expedited drug approvals often involve small clinical trials with a narrow patient population and trials are not regularly reported publicly. Once a drug enters the market, research into the long-term efficacy and side effects should continue within specific timeframes and reporting requirements. Even if a product is not approved, manufacturers should be required to report data for all trials that summarizes non-identifiable demographics and participant characteristics, primary and secondary outcomes results, and adverse event information.

- **Target exclusivity protections to the most innovative products.** Currently, pharmaceutical manufacturers can extend market exclusivity protections by seeking approval for a “new” product that is essentially the same as the original. Prohibiting such tactics will bring consumers more options and lower prices more quickly. Anti-competitive pricing schemes should be closely monitored by Federal agencies and prosecuted if violations of antitrust law are found.

- **Curb misuse of REMS.** As we noted above, the FDA uses REMS to allow products with potential safety issues to enter the market. Drug manufacturers often manipulate REMS to block generic drugs from obtaining samples of brand drugs under the guise of addressing patient safety concerns, effectively preventing them from pursuing the research needed to bring generic drugs to market. Bipartisan legislation has been introduced in both the Senate and the House—the CREATES Act and the FAST Generics Act—that would stop this anticompetitive practice. CSRxP encourages the committee to consider this bipartisan legislation that addresses these abuses by prohibiting companies from restricting sample access.

- **Promote a robust biosimilars market.** Regulatory policies should encourage market entry and uptake of biosimilars, as they have significant potential to expand treatment options and reduce costs by increasing competition in the marketplace. For example, one study found that 11 biosimilars already approved for sale in Europe and elsewhere could generate approximately \$250 billion in savings over 10 years if they were available in the United States.<sup>29</sup> We urge the committee to consider provisions—such as reducing the market exclusivity period for brand name biologics—that would help support the development of a robust biosimilar market and help ensure that patients have access to lower cost alternatives to existing, expensive biologics.

### 3. Incentivize Value

- **Increase funding for private and public research efforts like the non-profit Institute for Clinical and Economic Review (ICER) to test the value of medical tests and treatments.** Investment in objective information is critical for physicians, patients and payers as more and more high-price drugs enter the healthcare system.

- **Require drug makers to conduct comparative effectiveness research (CER) studies of new versus existing drug products.** Through CER studies, manufacturers should have to demonstrate that their product is better than others, so that physicians and patients can make smart decisions about the value of different treatments, particularly those with very high costs. Many other countries currently require drug manufacturers to provide CER studies; they should be expanded in the United States to reduce spending on unnecessary or ineffective treatments.

- **Expand value-based pricing in public health programs like Medicare and Medicaid.** Currently Medicare and Medicaid purchase prescription drugs for their beneficiaries, but not generally in a manner to accommodate value-based payment models. Steps should be taken to ensure these programs can best take advantage of recent developments in value-based purchasing to ensure all parts of the U.S. healthcare system benefit from market-based negotiating efforts to lower drug prices.

## VIII. CONCLUSION

In conclusion, CSRxP appreciates the leadership from the committee and again thanks the committee for the opportunity to submit testimony for the record to address the unsustainable and excessive growth in prescription drug costs in the

<sup>29</sup> Express Scripts. “The \$250 Billion Potential of Biosimilars.” April 23, 2013. See link: [http://lab.express-scripts.com/lab/insights/industry-updates/the-\\$250-billion-potential-of-bio-similars](http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-bio-similars)

United States. The Campaign looks forward to continued work with the committee in the future in developing market-based policies that promote competition, transparency, and value to make prescription drugs more affordable for all American patients and their families while at the same time maintaining access to the treatments that can improve health outcomes and save lives.

LOBBYING REGISTRATION FORM SUBMITTED BY SENATOR FRANKEN

Clerk of the House of Representatives Legislative Resource Center 5-106 Cannon Building Washington, DC 20515	Secretary of the Senate Office of Public Records 232 Hart Building Washington, DC 20510
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SECRETARY OF THE SENATE  
00 SEP -5 PM 4:44

### LOBBYING REGISTRATION

Lobbying Disclosure Act of 1995 (Section 4)

Check if this is an Amended Registration: ☐ I. Effective Date of Registration: 08/01/2009

2. House Identification Number: \_\_\_\_\_ Senate Identification Number: \_\_\_\_\_

#### REGISTRANT

3. Registrant Name: **PRESTON GATES ELLIS & ROUVILAS NEEDS LLP**

Address: **1735 NEW YORK AVE, NW SUITE 500**

City: **WASHINGTON** State: **DC** Zip: **20006**

4. Principal place of business (if different from line 3)  
City: \_\_\_\_\_ State/Zip (or Country): \_\_\_\_\_

5. Telephone number and contact name: **202-638-1706 ROSANNE PHILLIPS** Contact: \_\_\_\_\_ E-Mail (optional): \_\_\_\_\_

6. General description of registrant's business or activities:  
**Law Firm**

#### CLIENT

*A lobbying firm is required to file a separate registration for each client. Organizations employing in-house lobbyists should check the box labeled "Self" and proceed to line 10. ☐ Self*

7. Client Name: **Commonwealth of the Northern Mariana Islands**

Address: **Office of the Governor** **Cañon Box 10007**

City: **Saipan** State: **MP** Zip: **96950**

8. Principal place of business (if different from line 7)  
City: \_\_\_\_\_ State/Zip (or Country): \_\_\_\_\_

9. General description of client's business or activities:  
**United States Territory.**

#### LOBBYISTS

10. Name of each individual who has acted or is expected to act as a lobbyist for the client identified on line 7. If any person listed in this section has served as a "covered executive branch official" or "covered legislative branch official" within two years of first acting as a lobbyist for this client, state the executive and/or legislative position(s) in which the person served.

Name	Covered Official Position (if applicable)
JACK ABRAMOFF	
TODD BOULANGER	Legis. Aide - Sen. Bob Smith
WERNER BRANDT	
DARRYL A. CONNER	

Registrant Name: PRESTON GATES ELLIS & ROUVELAS MEEDS LLP

Client Name: Commonwealth of the Northern Mariana Islands

Item	Description	Data
10a	Lobbyist Name	DAVID FUNDERBORK
10b	Covered Official Position	CONGRESSMAN
10a	Lobbyist Name	BRUCE WEIMAN
10b	Covered Official Position	
10a	Lobbyist Name	WILLIAM JARRELL
10b	Covered Official Position	
10a	Lobbyist Name	LLOYD MEEDS
10b	Covered Official Position	
10a	Lobbyist Name	SOL MOSKOW
10b	Covered Official Position	
10a	Lobbyist Name	RALPH NURNBERGER
10b	Covered Official Position	
10a	Lobbyist Name	MICHAEL O'NEIL
10b	Covered Official Position	
10a	Lobbyist Name	TIM PECKINPAUGH
10b	Covered Official Position	
10a	Lobbyist Name	PATRICK PIZZELLA
10b	Covered Official Position	
10a	Lobbyist Name	KEYIN RING
10b	Covered Official Position	Ex. Dir. Hs. Comm. Act Team; Counsel US Sen. Jud. Com
10a	Lobbyist Name	EMANUEL ROUVELAS
10b	Covered Official Position	
10a	Lobbyist Name	ALAN SLOMOWITZ
10b	Covered Official Position	
10a	Lobbyist Name	DENNIS STEPHENS
10b	Covered Official Position	
10a	Lobbyist Name	STEVEN VALENTINE
10b	Covered Official Position	Leg. Dir. & Gen. Counsel Sen. Bob Smith
10a	Lobbyist Name	SHAWN VASELL
10b	Covered Official Position	
10a	Lobbyist Name	PADGHT WILSON
10b	Covered Official Position	Legis. Comm. Sen. Paul Coverdell

Registrant Name: **FRISTON GATES ELLIS & ROQUELAS MEEDS LLP**

Client Name: **Commonwealth of the Northern Mariana Islands**

### LOBBYING ISSUES

11. General lobbying issue areas. Select all applicable codes listed in instructions and on the reverse side of Form LD-1, page 1.

INM, LBR, TAX

12. Specific lobbying issues (current and anticipated)

### AFFILIATED ORGANIZATIONS

13. Is there an entity other than the client that contributes more than \$50,000 to the lobbying activities of the registrant in a substantial period and in whole or major part plans, supervises, or controls the registrant's lobbying activities?

☐ No. Go to line 14. ☒ Yes. Complete the rest of this section for each entity meeting the criteria above; then proceed to line 14.

Name	Address	Principal Place of Business (city and state or country)
Western Pacific Economic Council	P.O. Box 144 Saipan, MP 96950	

### FOREIGN ENTITIES

14. Is there any foreign entity that:

- a) holds at least 20% equitable ownership in the client or any organization identified on line 13; or
- b) directly or indirectly, in whole or in major part, plans, supervises, controls, directs, finances, or subsidizes activities of the client or any organization identified on line 13; or
- c) is an affiliate of the client or any organization identified on line 13 and has a direct interest in the outcome of the lobbying activity?

☒ No. Sign and date the registration. ☐ Yes. Complete the rest of this section for each entity meeting the criteria above; then sign and date the registration.

Name	Address	Principal Place of Business (city and state or country)	Amount of contribution for lobbying activities	Ownership percentage in client

Signature:  Date: **09/05/2000**

Printed Name and Title: **MICHAEL O'NEILL - ATTORNEY**

Form LD-1 (Rev. 04/98)

Registrant Name: PRESTON GATES ELLIS & ROUVELAS MEEDS LLP

Client Name: Commonwealth of the Northern Mariana Islands

Item	Description	Data
12	Specific Lobbying Issues	H.R.736; United States Commonwealth of the Northern Mariana Islands Human Dignity Act; S.1052; Northern Mariana Islands Covenant Implementation Act. H.R. 325; Fair Minimum Wage Act of 1999. S.192; Fair Minimum Wage Act of 1999. S.922; Made in the USA Label Defense Act of 1999; H.R.1671; Made in the USA Label Defense Act of 1999; Legislation affecting the tax status of goods produced in the Commonwealth of the Northern Mariana Islands. Legislation affecting the minimum wage in the Commonwealth of the Northern Mariana Islands.

#### RESPONSE BY DAN MENDELSON TO QUESTIONS OF SENATOR ALEXANDER

*Question 1.* To confirm feedback received at the hearing, I have heard that drug spending accounts for roughly 15 percent of health spending. Of that 15 percent, 10 to 11 percent is on drugs purchased at the pharmacy or ordered online, and 4 to 5 percent is spent on drugs given in a hospital or at the doctor's office.

Do you agree, that is how much is spent on drugs in the United States?

Answer 1. Those statistics are generally accurate, though estimates vary based on source and spending categories analyzed. According to the Centers for Medicare and Medicaid Services, National Health Expenditure Data, drugs dispensed in the pharmacy and medical benefit account for approximately 13 percent of total U.S. healthcare costs. This frequently cited figure uses total national health expenditures as a basis for calculating the percentage. Other experts sometimes use a subset of national health expenditures or total medical claims as the denominator, which accounts for the range of percentages often cited in this context.

*Question 2.* In 2015, 89 percent of all prescriptions picked up at pharmacy or online were low-cost generic drugs. According to Adam Fein, an expert on drug spending and the delivery system, nearly 30 percent of brand and generic prescriptions had a \$0 out-of-pocket cost for the patient in 2016, up from 11 percent in 2011. So there appears to be a growing number of prescriptions available at no cost to a patient when you pick up your prescription at the drug store. Do you agree with that statement?

Answer 2. I agree that the majority prescriptions filled at the pharmacy or online are generic drugs and that generic drugs typically have lower associated cost sharing for patients.

*Question 3.* Would it be accurate to say a drug list price does not accurately reflect costs to patients? What should we as Congress be focusing on, instead of list prices?

Answer 3. Generally, a drug's list price and actual patient costs differ based on a series of negotiations and decisions. Specifically, as multiple products for a given indication come to market, plans and PBMs may negotiate rebates and other price concessions from manufacturers in exchange for preferred formulary placement and improved access. Typically, payers use these price concessions to reduce overall premiums, but the rebates are not shared directly with patients at the point of sale. As a result, most patients who fill a prescription are paying cost-sharing based on a price that is generally not reflective of rebates negotiated by a health plan or PBM.

*Question 4.* Can you comment on whether the costs for drugs have gone up, down, or remained steady in the last 5 to 10 years?

Answer 4. Like spending for all medical services, spending on prescription drugs has increased over time as innovation has enhanced capabilities. In recent years, new innovations have increased spending on specialty medications, which now account for \$384 of the \$895 per person per year spent on drugs. However, list prices (11.5 percent) have increased more slowly than net prices (6.1 percent) over the past 5 years.

*Question 5.* We hear quite a bit about a need to have more transparency around drug prices and within the drug delivery system. Do you think transparency would help, and if so, where?

Answer 5. The impact of transparency proposals depends on how they are constructed. In some areas, price transparency causes consumers to make better competitive decisions, which could potentially result in lower costs. On the other hand, certain types of transparency requirements can present challenges, and have the potential to inhibit competition and create market distortions. For example, the Congressional Budget Office (CBO) estimates that disclosure of drug rebate information “would facilitate tacit collusion among those manufacturers, which would tend to raise drug prices.”

*Question 6.* We hear a lot about passing on rebates directly to consumers. What is your perspective on this proposal and what would be the impact on costs (for drugs or their premium) to patients?

Answer 6. Rebates have been growing in recent years, and generally are not passed on to consumers in the form of lower copays, but rather used to reduce premiums in the context of competitive markets. There is good potential to find ways to use rebates to reduce patient-cost sharing. While this type of proposal may lead to a small increase in premiums, the impact of the proposal on patient-cost sharing will depend on the structure of the policy and the healthcare needs of a particular patient. Undoubtedly, patients with chronic illnesses would benefit from this type of change, and point-of-sale adjudication/estimation of rebates is technically feasible.

*Question 7.* Can you comment on what tools are available within the delivery system to directly reduce patient costs?

Answer 7. Increased competition in the pharmaceutical markets holds promise for reducing costs. Speeding the approval of the second- and third-branded drugs in a therapeutic class would expedite competition and lead to more rapid price concessions. Ensuring a continued robust market for generic pharmaceuticals is vital for effective cost management and improvement of population health outcomes.

In addition, outcomes-based contracts also represent a significant opportunity to shift away from prescription drug list prices toward value-based reimbursement models. Effective outcomes-based contracts require next-generation data analysis and interventions that enable payers and manufacturers to identify patients eligible for treatment, target outreach to ensure appropriate adherence and quality improvement, and measure product performance against pre-agreed-upon outcomes on an ongoing basis. Consumer benefit can be substantially enhanced through data-based engagement around pharmaceuticals.

*Question 8.* What do you think of the suggestion that concerns related to drug costs have grown as patients have been forced personally to take on more and more of the drug costs?

Answer 8. Insurance benefit designs increasingly expose consumers to the full cost of their medicines through deductibles or percentage coinsurance for drugs, as payers have been under pressure to meet consumer demand for constrained premium growth. Of course, other factors also contribute to increased consumer payments, such as the cost of newly launched products and the increases in list prices over time.

#### RESPONSE BY ALLAN COUKELL TO QUESTIONS OF SENATOR ALEXANDER

*Question 1.* To confirm feedback received at the hearing, I have heard that drug spending accounts for roughly 15 percent of health spending. Of that 15 percent, 10 to 11 percent is on drugs purchased at the pharmacy or ordered online, and 4 to 5 percent is spent on drugs given in a hospital or at the doctor's office. Do you agree, that is how much is spent on drugs in the United States?

Answer 1. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimates that pharmaceuticals accounted for almost 17 percent of U.S. personal health care services, or \$457 billion, in 2015—retail and mail order prescription drugs accounted for 12 percent of personal health care services, while nearly 5 percent was for pharmaceuticals given in the hospital, physician's office and other non-retail settings.<sup>1</sup> The Altarum Institute, a nonprofit health organization, estimates that retail and non-retail prescription drug spending totaled \$450 billion in

<sup>1</sup> While Altarum and ASPE use similar methodologies, Altarum utilizes total health expenditure as a denominator, and ASPE uses personal health care expenditure. Personal health expenditure represents spending on medical care and excludes government spending on administration, public health, and investment into medical research. Personal health expenditure in 2015 was \$2.72 trillion.

2016, or 14 percent of health expenditures.<sup>2</sup> Of total health expenditure, 10.1 percent was for retail spending on pharmaceuticals, and 4.3 percent was for non-retail spending.<sup>3\*</sup>

*Question 2.* In 2015, 89 percent of all prescriptions picked up at pharmacy or online were low-cost generic drugs. According to Adam Fein, an expert on drug spending and the delivery system, nearly 30 percent of brand and generic prescriptions had a \$0 out-of-pocket cost for the patient in 2016, up from 11 percent in 2011. So there appears to be a growing number of prescriptions available at no cost to a patient when you pick up your prescription at the drug store. Do you agree with that statement?

*Answer 2.* The growth in the share of prescriptions with no out-of-pocket costs for patients is driven by generics. An IMSQuintiles analysis found that last year 26 percent of prescriptions dispensed were for generic drugs with no out-of-pocket costs.<sup>4</sup> An additional 3.9 percent of prescriptions were for brand drugs with no out-of-pocket costs. Insurance plan design determines out-of-pocket costs for any individual patient, but other policies also contribute. For example, most Medicaid patients have zero dollar or low out-of-pocket costs and the Affordable Care Act (ACA) requires generic contraceptives to be dispensed with no out-of-pocket costs. In addition, the ACA limits annual patient out-of-pocket spending for covered services in a health plan, including that of prescription drugs. Prescriptions dispensed for patients who have surpassed their annual maximum have no out-of-pocket costs.

However, some patients have seen their out-of-pocket costs increase significantly in recent years. The number of Medicare Part D enrollees reaching the catastrophic coverage phase reached 3.6 million in 2015, a 53 percent increase since 2010.<sup>5</sup> Enrollees not eligible for a low-income subsidy must pay 5 percent of the cost of their prescriptions in the catastrophic coverage phase, with no limit on annual out-of-pocket spending. In 2015 patients reaching the catastrophic coverage phase paid an average of \$257 per month for each high cost prescription drug—defined as medications with an average price of more than \$1,000 per month.

*Question 3.* Would it be accurate to say a drug list price does not accurately reflect costs to patients? What should we as Congress be focusing on, instead of list prices?

*Answer 3.* List prices are a critical factor in determining out-of-pocket costs for many patients. This happens in at least three circumstances. (1) Patients without drug coverage are charged something close to list price at the pharmacy, even when the price paid by larger payers is far lower. (2) Patients enrolled in health plans with deductibles must pay the full cost of their medications until they meet an annual spending threshold. During this deductible phase, out-of-pocket payments are typically based on the drug's list price. (3) Patients in health plans with co-insurance,<sup>6</sup> which is usually applied to the most expensive prescriptions medications, typically pay a fixed percentage (e.g., 30 percent) of the drug's list price.

Among commercially insured patients in 2016, over half of patient out-of-pocket costs for brand prescriptions was based on list prices, and over 90 percent of patient out-of-pocket spending for specialty drugs was based on list prices.<sup>7</sup> While some payers are able to offer plans that pass on rebates and discounts off the drug list price to patients at the point of sale,<sup>8</sup> it is unknown to what extent plan sponsors are choosing these benefit designs.

<sup>1</sup> Health and Human Services Assistant Secretary for Planning and Evaluation, "Observations on Trends in Prescription Drug Spending," March 2016, Available at: <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>.

<sup>2</sup> C. Roehrig, "Center for Sustainable Health Spending Data Brief: A Ten Year Projection of the Prescription Drug Share of National Health Expenditures Including Non-Retail," Altarum (Updated May 2017), <http://altarum.org/publications/a-10-year-projection-of-the-prescription-drug-share-of-national-health-expenditures-including>.

<sup>3</sup> Ibid.

<sup>4</sup> QuintilesIMS Institute, "Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021," May 2017, Available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>.

<sup>5</sup> Department of Health and Human Services, Office of the Inspector General, "High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage," January 2017, Available at: <https://oig.hhs.gov/oei/reports/oei-02-16-00270.pdf>.

<sup>6</sup> This differs from copays, under which patients pay a fixed dollar amount for a prescription.

<sup>7</sup> QuintilesIMS Institute, "Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021," May 2017, Available at: <http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>.

<sup>8</sup> CVSHealth, Consumer Transparency Helping Members with High-Cost Drugs at the Point of Sale, <https://payorsolutions.cvshealth.com/insights/consumer-transparency>.

Congress should focus primarily on overall drug spending, particularly in public programs. However, drug list prices are not an accurate measure of total U.S. spending on prescription drugs. Some organizations have published estimates for total drug spending, but each uses a different approach, some focusing on pharmaceutical manufacturer revenue, while others are based on pharmacy claims, which often do not take into account rebates and other discounts offered by manufacturers. One challenge in understanding drug spending is the range of entities involved in the prescription drug supply and payment chain, including wholesalers, pharmacy benefit managers, pharmacies, and insurers. Each of these entities retains a portion of total drug spending and flow of health care payer and consumer dollars throughout this complex system is little understood.

However, list prices are useful in establishing trend lines for prescription drug spending, as list and net prices tend to rise in tandem (though the average gap between list and net prices has increased slightly in recent years as rebates have increased).

Pew is pursuing additional research that will develop a national estimate of total spending on drugs, including contributions toward insurance premiums for drug coverage and a breakdown of what share of this total each supply chain entity retains.

*Question 4.* Can you comment on whether the costs for drugs have gone up, down, or remained steady in the last 5 to 10 years?

Answer 4. The costs for drugs have gone up in recent years. As discussed, methodologies vary widely, but there is widespread agreement that spending on drugs has increased significantly. A 2016 report by the Department of Health and Human Services Assistant Secretary for Planning and Evaluation found that “[e]xpenditures on prescription drugs are rising and are projected to continue to rise in the coming years as a share of total health care spending.”

IMSQuintiles estimates that drug manufacturer revenue net of rebates and discounts has increased 42 percent since 2006, reaching \$323 billion in 2016, with more than two-thirds of that growth occurring since 2013.<sup>9</sup> They have found that while both drug list prices and rebates and discounts to payers have increased substantially year over year, manufacturer net revenue has continued to rise, up 4.8 percent in 2016 alone.

New brand drugs have driven the majority of this spending growth each year since 2014. New drugs are increasingly specialty products, including biologics, and typically launch at high prices. Year-on-year increases in the prices of brand drugs that do not yet face generic competitors also contribute to rising spending. Conversely, spending on generic drugs decreased slightly in 2016. Generic drugs represent an ever-growing share of prescriptions dispensed, reaching over 89 percent in 2016. While there have been some individual generic products with extraordinary price increases in recent years, generic drugs as a class generate significant savings.

*Question 5.* Some have suggested that drug importation could lower drug prices. What are your views on that strategy?

Answer 5. Brand pharmaceuticals are generally more expensive in the United States than in other high-income countries, in part because some countries have implemented policies to limit prices, so allowing the purchase and importation of prescription drugs from other countries has the potential to give Americans access to some medicines at lower prices.<sup>10</sup> However, it is difficult to estimate the potential savings, which would have to be weighed against the costs to implement such a program, the potential safety risks of imported products, and the overall impact on the security of the U.S.-drug supply chain.

The importation of drugs from foreign sources would bypass current FDA review processes and could increase safety risks. Federal law currently provides the Secretary of Health and Human Services the authority to permit importation of prescription drugs from Canada, if the Secretary certifies to Congress that they would pose no additional risk to the public’s health and safety, and would result in a significant reduction in the cost of the drugs to Americans. However, no certification has ever been made.

To address the potential risks associated with importing unapproved drugs, FDA would need significant additional resources and capacity. At a 2004 congressional hearing, FDA’s then-commissioner speculated that a program to ensure the safety

<sup>9</sup> QuintilesIMS Institute, “Medicines Use and Spending in the U.S.: Review of 2016 and Outlook to 2021,” May 2017, Available at: <http://www.imshealth.com/en/thought-leadership/quintiles-ims-institute/reports/medicines-use-and-spending-in-the-us-review-of-2016-outlook-to-2021>.

<sup>10</sup> The Pew Charitable Trusts, “Policy Proposal: Importation of Prescription Drugs,” <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2017/04/policy-proposal-importation-of-prescription-drugs>.

of imported drugs could cost hundreds of millions of dollars annually,<sup>11</sup> which could reduce the net savings from importation.

Furthermore, any importation system would need to conform to the requirements of the Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act of 2013), which Congress passed to ensure that counterfeit and diverted drugs do not enter the pharmaceutical supply chain. This legislation requires pharmaceutical manufacturers and repackagers to put a unique product identifier on most prescription drug packages and outlines steps to build a system for electronically identifying and tracing each individual package of prescription drug as it is distributed in the United States. Manufacturers must put this unique code on products beginning November 2017, and by 2023, all participants in the pharmaceutical supply chain must participate. This will make it easier to detect when counterfeit or illegal product is introduced into the system, and will significantly enhance the speed and accuracy of implementing product recalls. However, if imported product could be sold into the U.S. system without the product identifiers necessary to comply with this drug security system, it would make it difficult for supply chain partners who encounter product that is not compliant to determine which products are counterfeit or otherwise illegal, and which are legally imported. As a consequence, the risk of importation is not only that FDA cannot ensure that the products being imported are legitimate, but that the introduction of products that are not a part of the supply chain security system (even if they are legitimate products) will compromise the ability of the system to identify counterfeit and diverted products from any source, thus significantly undermining the protections that Congress put into place in 2013.

The importation of drugs from abroad could also have unintended consequences in other countries. The U.S. population far exceeds that of most other OECD countries and therefore meeting even a portion of U.S. demand with foreign supplies could strain local markets. To mitigate decreased U.S. revenue, manufacturers could seek to increase their prices in foreign markets or restrict foreign entities from exporting medications to the United States. In addition, the U.S. market's large size could strain the supply of pharmaceuticals, resulting in drug shortages in other countries if importation were to be implemented on a large scale.

#### RESPONSE BY PAUL HOWARD TO QUESTIONS OF SENATOR ALEXANDER

*Question 1.* To confirm feedback received at the hearing, I have heard that drug spending accounts for roughly 15 percent of health spending. Of that 15 percent, 10 to 11 percent is on drugs purchased at the pharmacy or ordered online, and 4 to 5 percent is spent on drugs given in a hospital or at the doctor's office. Do you agree, that is how much is spent on drugs in the United States?

Answer 1. Yes, although the exact numbers vary by source. In 2015, *APSE estimated* that prescription drug spending in the United States was about \$457 billion in 2015. That same year, *CMS found* that U.S. health care spending totaled \$3.2 trillion, which would put total prescription drug (retail and physician-administered) spending at 14.28 percent for 2015. ASPE also notes that 70 percent of the increase in spending from 2010–14 was due to non-price-related factors (i.e., 10 percent population growth, 30 percent increase in the number of prescriptions per person, 30 percent overall, economy-wide inflation). By way of comparison, in 2016, the *Kaiser Family Foundation* found that retail pharmacy sales totaled \$379 billion or 11.1 percent of the total health care spending (\$3.4 trillion) in the United States for that year.<sup>12</sup>

Finally, totally net spending growth has *slowed considerably* since 2014, according to a May 2017 report from Quintiles/IMS (slide 1).

*Question 2.* In 2015, 89 percent of all prescriptions picked up at pharmacy or online were low-cost generic drugs. According to Adam Fein, an expert on drug spending and the delivery system, nearly 30 percent of brand and generic prescriptions had a \$0 out-of-pocket cost for the patient in 2016, up from 11 percent in 2011. So there appears to be a growing number of prescriptions available at no cost to a patient when you pick up your prescription at the drug store. Do you agree with that statement?

<sup>11</sup>Options for Safe and Effective Prescription Drug Importation: Hearing Before the Committee on Commerce, Science, and Transportation, U.S. Senate, 108th Cong. (2004) (statement of Mark McClellan, commissioner of the U.S. Food and Drug Administration), <https://www.gpo.gov/fdsys/pkg/CHRG-108shrg76522/pdf/CHRG-108shrg76522.pdf>.

<sup>12</sup><http://www.drugchannels.net/2016/04/key-insights-on-drug-prices-and.html>.

<sup>2</sup><http://www.drugchannels.net/2016/07/latest-cms-forecast-shows-big-drug.html>.

Answer 2. I agree. The 2017 Quintiles/IMS report *shows this* (see slide 5). However, the Quintiles report shows that patient out-of-pocket spending is highly concentrated among patients with certain formulary or benefit designs. Quintiles notes that plans with drug “deductibles and coinsurance set patient out-of-pocket costs based on list prices and 19 percent of commercial brand prescriptions are paid in this way, accounting for 52 percent of out-of-pocket costs.”

Specifically, “patients with a specialty prescription in the deductible accounted for 2 percent of prescriptions but 32 percent of out-of-pocket costs.” It is the concentration of OOP spending in a relatively small subset of patients that I find worrisome:

“Abandonment rates for brands are 2.5 times higher when the patient is in the deductible phase of their plan and sees the full cost of the medicine they have been prescribed.”

As I noted in my testimony, Congress’ attention should be focused on addressing potentially excessive patient-cost sharing that impact patients’ health outcomes.

*Question 3.* Would it be accurate to say a drug list price does not accurately reflect costs to patients? What should we as Congress be focusing on, instead of list prices?

Answer 3. That is correct. Data suggests that, net of rebates, drug price increases (on average) have been fairly modest. Congress should focus on insurance designs that increase patient-cost sharing without reflecting the rebates that manufacturers have negotiated with payers and PBMS.

Broadly speaking, we also need to ensure that insurers are not using formulary design (what drugs are covered, and what co-insurance they face) as a tool for *adverse selection*. Further, CMS and Congress should be carefully monitoring Part D plans, 340B, and exchange plans, to monitor insurance designs for potentially discriminatory impact.

However, this is a problem that will require a multi-stakeholder solution to further the bipartisan goal of expanding coverage, improving quality, and slowing cost growth across the health care system. I believe that Congress and the Administration should consider how to better encourage plans, manufacturers, and providers to take a longer term view of the role of medicines in keeping patients healthier, longer and reducing the use of other health care “inputs,” including hospitalizations and emergency rooms visits.

Encouraging the uptake of value-based insurance designs, longer term (multi-year) insurance contracts, and safe harbors from Federal regulations like Medicaid Best Price and Stark anti-kickback can help the market evolve toward competition based on patient outcomes, rather than short-term price of a pill.

Experts on both sides of the aisle agree that there is hundreds of billions of dollars in excessive spending that could be cut from the U.S. health care system, while also improving patient outcomes. The incentives for collaboration and competition based on delivering best-in-class outcomes more efficiently for every dollar spent, however, remain weak.

*Question 4.* Can you comment on whether the costs for drugs have gone up, down, or remained steady in the last 5 to 10 years?

Answer 4. Average prescription drug spending steadily decreased from 2000–14. The 2014 spike in spending is almost entirely attributable to the entry of highly effective, yet expensive, treatments for hepatitis C into the marketplace.

Out-of-pocket prescription drug spending decreased from 2005–10, and remained stagnant through 2015. While out-of-pocket spending is expected to increase in the coming years, it is also expected to represent a continuously smaller share of total health care spending. Many new treatments that are expected to come online in the next several years, like C-ART for blood cancers, or gene therapies, are expected to be highly beneficial for patients—and thus highly valuable for society. Building a sustainable framework for rapid adoption of curative therapies is both a tremendous challenge, and a tremendous opportunity.

*Question 5.* We hear quite a bit about a need to have more transparency around drug prices and within the drug delivery system. Do you think transparency would help, and if so, where?

Transparency matters when it encourages patients and physicians to find the most effective therapy for that patient, given their medical needs and treatment preferences.

Transparency around list prices isn’t helpful, since patient-cost sharing varies so widely based on plan design, or where the patient is within their annual deductible.

It also doesn’t help us understand the role medicines play in the wider health care system, where they are a vital tool for managing serious chronic illnesses that account for roughly 85 percent of U.S. health care costs.

Given the economics of the industry, we should also expect drug discounts to vary across payers—just as physician and hospital prices vary. There is no “one” right price for a medicine.

What we should be doing improving patients and physicians’ ability to compare treatment strategies based on real world costs, benefits, and risks. Real world data on patient outcomes would give us much greater ability to drive competition across medicines, other treatment strategies, and providers. We should have a health care system that rewards the delivery of the best patient outcome, as efficiently as possible—whether that is through better diet, exercise, medical management, or a surgical intervention. Transparency in terms of being able to track and share data on patient outcomes and costs (with appropriate privacy protections) would save lives and help reduce the enormous waste and inefficiency we see today across the U.S. health care system.

*Question 6.* We hear a lot about passing on rebates directly to consumers. What is your perspective on this proposal and what would be the impact on costs (for drugs or their premium) to patients?

To my knowledge, CVS is the only PBM that has *embraced* this approach, but I believe it would be helpful to address current patient-cost sharing burdens. Depending on the rebate—say 20 percent or 30 percent—it could help patients substantially who otherwise find themselves paying based on the list price.

Ultimately, we need to shift to a different system of paying for medicines that does not depend on formularies based on the “bubble” between the list and net price. This is a step in that direction, but other approaches should be tried as well, including new insurance designs and tools for right-sizing patient-cost sharing based on outcomes (i.e., *value-based insurance designs*).

*Question 7.* Can you comment on what tools are available within the delivery system to directly reduce patient costs?

Manufacturers often offer co-pay/co-insurance assistance programs, and other means-tested programs that cap the out-of-pocket costs that patients pay for their medicines. Some PBMs, like Express Scripts, have begun to offer discounts for *uninsured patients* who would otherwise pay list price for their medicines. These programs are a relatively new phenomenon. Premera Blue Cross/Blue Shield in Washington State has offered a *value-based formulary* for employers where co-pays vary not based on price, but on how effective the medicine is—a very interesting approach that is, however, *data intensive*.

Encouraging providers, payers, and manufacturers to routinely generate and collect more real world data on patients could lower the cost of implementing these approaches. To do so, however, would require regulatory safe harbors from some FDA and CMS regulations.

*Question 8.* What do you think of the suggestion that concerns related to drug costs have grown as patients have been forced personally to take on more and more of the drug costs?

Answer 8. There have been dramatic shifts in insurance design over the last decade, including the rise of high deductible health plans, and the passage of the Affordable Care Act. Under the ACA, as insurers have been forced to cover more routine costs without any patient-cost sharing, and to standardize other benefits (no annual or lifetime cap on benefits, covering a broader collection of essential health benefits, greater scrutiny of annual premium increases), and the rise of maximum caps on annual spending that combine both medical and the pharmacy deductibles, more drug costs are being shifted onto patients for certain categories of high cost medicines, even though the long-term trends are toward lower overall OOP for health care in general.

#### RESPONSE BY GERARD ANDERSON TO QUESTIONS OF SENATOR ALEXANDER

*Question 1.* To confirm feedback received at the hearing, I have heard that drug spending accounts for roughly 15 percent of health spending. Of that 15 percent, 10 to 11 percent is on drugs purchased at the pharmacy or ordered online, and 4 to 5 percent is spent on drugs given in a hospital or at the doctor’s office. Do you agree, that is how much is spent on drugs in the United States?

Answer 1. Yes, I agree with these numbers on drug spending. I would also add that, according to the Office of the Actuary in the Center for Medicare and Medicaid Services, prescription drug spending is expected to grow faster than overall health spending between 2016 and 2025 (an average of 6.3 percent per year compared to an average of 5.6 percent per year for overall health spending), which could affect these numbers moving forward.

As I highlighted in my testimony, these prescription drug costs are frequently passed onto patients, making it difficult for them to afford the medications that they need. For example, a Kaiser Family Foundation study found that for Medicare beneficiaries with Part D coverage, out-of-pocket costs averaged \$7,000 for drugs to treat hepatitis C, \$6,000 for drugs to treat multiple sclerosis, \$4,000 for drugs to treat rheumatoid arthritis and \$8,000 for drugs to treat certain types of cancer. For a social security recipient earning \$26,000 per year, these out-of-pocket costs represent 16 percent to 32 percent of the person's total income for the year and clearly are prohibitively expensive.

RESPONSE BY DAN MENDELSON TO QUESTION OF SENATOR ISAKSON

*Question.* What would be the anticipated impact of allowing patients to appeal for lower cost sharing if the drug they need (as determined by their doctor and following any plan imposed utilization management procedures) happens to be on a Part D plan's "specialty tier?" Because the patient would be paying a total lower out-of-pocket cost, wouldn't this common-sense policy be good both for the patient (lowered OOP cost) and for Medicare (slower progression through the benefit and into catastrophic)?

*Answer.* There is growing interest in aligning insurance design to deliver value to patients. In particular, some patients have responses to medications or genetic makeups that require them to take a drug on the specialty tier, even if lower cost options are available. While this proposal represents an opportunity to align benefit design and the patient experience to such considerations, it could also potentially have implications for the market. Allowing patients to appeal for lower cost sharing for specialty tier drugs in Part D would lower patient out-of-pocket costs for some beneficiaries. This policy also has the potential to reduce costs to the Medicare program, as patients may take longer to reach the catastrophic phase of the benefit, where Medicare pays a greater share of costs. However, such policy would also alter the costs incurred by health plans, which could impact premiums.

RESPONSE BY DAN MENDELSON TO QUESTIONS OF SENATOR SANDERS

*Question 1.* Since online pharmacies were created about 15 years ago, there have been no reported examples of Americans dying by taking medication bought online from a *legitimate* and *regulated* pharmacy in Canada that requires valid prescriptions. And, this is after tens of millions of prescriptions have been filled online and internationally.

During the hearing, however, you raised safety concerns when the topic of drug importation was raised by Senator Murkowski. And, you stated that there have been cases of Americans being harmed by drugs they imported.

Can you provide specific instances you referenced generally during your testimony? Where (both in terms of country and type of distributor) did these drugs come from? Were they from legitimate, regulated online pharmacies? Did the patients have a prescription from a licensed health care provider?

*Answer 1.* The safety concerns I raised during my oral comments regarding the importation of medication from outside of the United States are based on statements from the Congressional Budget Office, the Food and Drug Administration, and the Federal Bureau of Investigation.

The Congressional Budget Office stated,

"All products distributed in the United States must be produced in facilities registered with the FDA for production of those specific products. Much of existing worldwide sales volume does not satisfy that criterion, even drugs that otherwise meet safety and efficacy standards."<sup>1</sup>

For example in March 2017, 4 former Food and Drug Administration commissioners warned Congress that legalizing importation of drugs from other countries could endanger consumers by exposing them to fake, substandard, or contaminated drugs. The commissioners were concerned that there is no reliable way of knowing where imported drugs come from, particularly since the vast majority of online pharmacies are fake.<sup>2</sup>

Recently, the former director of the Federal Bureau of Investigation, released a report examining the degree to which current drug importation proposals, if imple-

<sup>1</sup>The Congressional Budget Office. Would Prescription Drug Importation Reduce U.S. Drug Spending? April 2004. <https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/04-29-prescriptiondrugs.pdf>.

<sup>2</sup><https://assets.documentcloud.org/documents/3519007/FDA-Commissioners-Drug-Reimportation.pdf>.

mented, would impact law enforcement’s ability to protect the public health and ensure the safety of our drug supply. That report concluded that “importation proposals would force law enforcement agencies to make tough prioritization decisions that leave the safety of the U.S. prescription drug supply vulnerable to criminals seeking to harm patients.”<sup>3</sup>

*Question 2.* In a January 2017 article published in “Chicago Business” you are credited with predicting that GOP legislators would follow President Trump’s lead on drug pricing after the President commented that prescription drug companies were “getting away with murder.” You also are credited with pointing out that pre-election poll data showed that Republican voters care more about high drug prices than they did about repealing Obamacare. In fact, you are quoted as saying, “it’s a populist issue” and one that “Trump is likely to move on.”

My question is this: What is the best way for this issue to be addressed to ensure that drug companies do not continue “getting away with murder” and that the interests of the Republican voters you referenced in your article—lower high drug prices over repealing Obamacare—are front and center?

Answer 2. There are a range of opportunities to shift toward models that align drug prices to value, by promoting competition and pursuing other market-driven solutions. In particular, speeding the approval of the second- and third-branded drugs in a therapeutic class would expedite competition and lead to more rapid price concessions. Ensuring a continued robust market for generic pharmaceuticals is vital for effective cost management and improvement of population health outcomes.

In addition, outcomes-based contracts also represent a significant opportunity to shift away from prescription drug list prices toward value-based reimbursement models. Effective outcomes-based contracts require next-generation data analysis and interventions that enable payers and manufacturers to identify patients eligible for treatment, target outreach to ensure appropriate adherence and quality improvement, and measure product performance against pre-agreed-upon outcomes on an ongoing basis. Consumer benefit can be substantially enhanced through data-based engagement around pharmaceuticals.

#### RESPONSE BY PAUL HOWARD TO QUESTIONS OF SENATOR SANDERS

*Question 1.* Dr. Howard, it is my understanding that the Manhattan Institute believes very strongly in the value of free trade. As you know, the United States safely imports lettuce, strawberries, tomatoes, fish and shrimp, and many other foods from Mexico, Singapore and other countries in Southeast Asia. For the most part, do you believe these fruits and vegetable and seafood are safe?

We do believe strongly in the value of free trade and free markets, and competition as a tool to drive value for consumers and patients.

However, with all due respect, the complexity of the drug supply chain—as demonstrated by recent scandals with fake or adulterated medicines originating in China or India—and the risks associated with patients receiving such fake or adulterated medicines for serious diseases *like cancer* are simply an order of magnitude higher than for foods. The economic incentive for sophisticated counterfeiters to find ways to slip fake medicines into higher cost markets like the United States are extraordinarily powerful, *and growing*. Opening the closed U.S. drug supply chain would increase these problems dramatically.

Issues with food safety are more easily detectable than in the case of chronically ill patients who may ingest fake or adulterated drug products imported from abroad, because they are already in compromised health. If a patient with high cholesterol or high blood pressure takes a fake medicine, the results may not be detected without regular testing—which might not occur for months, leaving the patient at increased risk of a serious adverse event. The progression of cancer might also go undetected for some time, and death could be attributed to the aggressiveness of the disease, rather than the use of counterfeit medicines.

Opening up the U.S. market to the wholesale importation of medicines from abroad has never been certified as safe by any FDA Commissioner from either a Republican or Democratic *administration*. Given the much smaller populations in Canada, or the UK, and the need for those populations to consume medicines for their own market, implies that extra quantities for the U.S. market would have to be generated by re-sellers from much farther abroad. This opens up opportunities for *fraud*, as has been the case in the EU.

<sup>3</sup>Freeh, Sporkin and Sullivan LLC, Freeh Group International Solutions LLC. Report on the Potential Impact of Drug Importation Proposals on U.S. Law Enforcement. March 2017 <http://freepdfhosting.com/84170a76e7.pdf>.

Finally, I would note that attempting to link drug prices in wealthier countries to lower cost drug sales in poorer countries (again, as occurs in the EU, under parallel trade, where drugs for the UK and Germany are imported from poorer countries like Greece) provides an incentive for manufacturers to delay the launch of new medicines in poorer countries, or raises the prices lower income nations pay.

Respectfully, I would suggest that this is the wrong way to address pricing challenges facing U.S. patients. Wealthier countries *should* pay higher prices for medicines than poorer countries, and attempting to arbitrage away the differences will only reduce the total supply of innovations available to future patients in both wealthy and poor countries alike. Instead, we should be finding ways to reduce unnecessary patient-cost sharing in the United States in ways that actually improve long-term patient health, as has been *suggested* by economists at RAND.

*Question 2.* If Americans can eat food from what some would call “developing nations,” then shouldn’t Americans be able to import safe and affordable prescription drugs, from regulated and legitimate pharmacies, from a “developed” nation like Canada? And, do you agree—yes or no—that Americans should have confidence in the safety of Canadian drugs much like they have confidence in the safety of shrimp from Singapore or lettuce and strawberries from Mexico? Please explain your answer.

*Answer 2.* Please see my answer to the previous question. I do not believe that the prices of poorer countries, like Mexico, should be linked to the sales of medicines in wealthier countries like the United States.

Differential pricing of medicines in wealthier and poorer countries is not only economically efficient, it raises the global supply medical innovations and thus global health.

To put this another way, wealthy countries subsidize drug development for poorer and middle income countries. Linking these markets is likely to raise prices for poorer countries beyond their ability *to pay*.

The economics and regulation of the pharmaceutical industry are simply very different than commodities like food. And the different size of the United States and Canadian markets makes it impossible for Canada to supply any significant part of U.S. market. As noted earlier, keeping a closed system would be virtually impossible.

#### RESPONSE BY GERALD ANDERSON TO QUESTIONS OF SENATOR SANDERS

*Question 1.* Dr. Anderson, you make it very clear in your testimony that a lack of transparency about drug pricing is a major part of the drug pricing crisis in the United States. Drug companies do not have to offer any transparency. In fact, they set a list price without being regulated or constrained. PBMs also are able to hide behind a zero transparency climate. In fact, despite what they claim to do, PBMs have a financial incentive to try to get drug companies to increase their list prices because they, then, make a greater profit. Wholesalers bring pharmaceutical drugs to hospitals and pharmacies, and they earn a profit in doing so without disclosing the amount. And, pharmacies and hospitals sell drugs to patients, and they make a profit in doing so, too. At the end of the day, the person who really pays is the patient and they often do so through higher cost sharing.

Dr. Anderson, as we work to expand transparency and to bring all of these varying amounts of money out into the open, do you think that we need to implement a drug importation system so that Americans can afford the medicines that they need today?

In regards to importation, my concern is that the pharmaceutical industry would likely adapt to any policy change in this area by rationing the number of drugs that they send to Canada or other countries. As a result, U.S. patients could still struggle to obtain needed medications, while creating access and affordability issues for patients in these other countries. Additionally, patients could face increased safety risks by consuming medications from manufacturers and countries outside of the current FDA-approval system.

However, I do think it is important to allow importation for off-patent drugs that have three or fewer competitors. I talked about this issue in my congressional testimony at the Senate Aging Committee and was a coauthor of a JAMA paper on this topic as well (Greene, Jeremy A., Gerard Anderson, and Joshua M. Sharfstein. “Role of the FDA in affordability of off-patent pharmaceuticals.” *Jama* 315.5 (2016): 461–62.) It turns out that most of these drugs are being manufactured in other highly industrialized countries and it would be very easy to import these drugs from other countries without having the drug companies be able to penalize the other countries.

Instead, I would suggest looking at other policy changes that could quickly bring down drug prices and increase patients' access to the medications that they need, such as enacting price gouging legislation that empowers State Attorneys General to take legal actions against drug companies, restricting "pay for delay" behavior and other similar tactics that block generic drug companies from entering the marketplace, or using the Federal Government's current authority under 28 U.S.C. §1498 to provide reasonable compensation to a drug company for the use of its patent and allow a generic manufacturer to manufacture the drug.

[Whereupon, at 12:22 p.m., the hearing was adjourned.]

